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# (54) ATRIAL POCKET CLOSURES FOR PROSTHETIC HEART VALVES

ATRIALE TASCHENVERSCHLÜSSE FÜR HERZKLAPPENPROTHESEN

FERMETURES DE POCHE AURICULAIRE POUR VALVULES CARDIAQUES PROTHÉTIQUES

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EP 3 397 206 B1

## Description

*Cross-Reference to Related Applications*

*Background*

**[0001]** Prosthetic heart valves, including those for insertion into atrioventricular valves (tricuspid and mitral valves) are susceptible to various problems, including problems with insufficient articulation and sealing of the valve within the native valve annulus, pulmonary edema due to poor atrial drainage, perivalvular leaking around the install prosthetic valve, lack of a good fit for the prosthetic valve within the native valve annulus, atrial tissue erosion, excess wear on the Nitinol structures, interference with the aorta at the anterior side of the mitral annulus, lack of customization, and thrombus formation, to name a few. Accordingly, there is a need for a prosthetic heart valve that can address some or all of these problems.

**[0002]** Moreover, there are a variety of different delivery approaches for delivering and deploying a prosthetic heart valve into atrioventricular valves and depending on the delivery approach the desired features and structure of a prosthetic heart valve can vary. For example, in transvascular delivery of a prosthetic heart valve it is desirable to have a prosthetic heart valve that can have an expanded configuration for implantation within the heart and a collapsed or compressed configuration that has a sufficiently small outer perimeter or diameter to allow the prosthetic heart valve to be placed in a relatively small delivery catheter or sheath. In such embodiments of a prosthetic heart valve, it is also desirable for features of the prosthetic heart valve, such as those described above, to be maintained.

**[0003]** WO 2014/210124 A1 describes a prosthetic heart valve which may include an outer support assembly, an inner valve assembly, which define between them an annular space, and a pocket closure that bounds the annular space to form a pocket in which thrombus can be formed and retained.

**[0004]** US 2015/0327995 A1 describes a prosthetic heart valve including a collapsible and expandable stent extending from an inflow end to an outflow end and a plurality of prosthetic valve leaflets coupled to the stent. The prosthetic heart valve may also include a sealing ring coupled to the inflow end of the stent, the sealing ring comprising a tube extending circumferentially around the inflow end of the stent.

**[0005]** WO 2015/120122 A2 describes apparatus and methods for use in the transfemoral delivery and deployment of a prosthetic mitral valve, wherein a method may include inverting an outer frame of a prosthetic mitral valve when in a biased expanded configuration.

**[0006]** WO 2014/144937 A2 describes prosthetic heart valve devices for pay cutaneous replacement of native heart valves and associated systems and methods, wherein a prosthetic heart valve device may include an anchoring member having an upstream portion configured to engage with tissue on or near the annulus of the native heart valve and to deform in a non-circular shape to conform to the tissue. The device can also include a mechanically isolated valve support coupled to the anchoring member and configured to support a prosthetic valve.

Summary

**[0007]** The invention relates to a prosthetic heart valve and is defined in the appended claims. According to the invention, the prosthetic heart valve includes an outer frame coupled to an inner frame such that the outer frame can be moved between a first position relative to the inner frame and a second position relative to the inner frame in which the outer frame is inverted relative to the inner frame. The inner frame and the outer frame define between them an annular space. In some embodiments, a pocket closure bounds the annular space to form a pocket in which thrombus can form and be retained. The pocket closure can include a stretchable pocket covering that can move from a first position in which the pocket covering has a first length when the outer frame is in the first position relative to the inner frame and a second position in which the pocket covering has a second length greater than the first length when the outer frame is in the second position relative to the inner frame.

*Brief Description of the Drawings*

**[0008]**

FIGS. 1A and 1B are a schematic perspective view and a side cross-sectional view, respectively, of a prosthetic heart valve, according to an embodiment.

FIGS. 2A is a schematic perspective view, of an inner valve assembly of the prosthetic heart valve of FIGS. 1A and 1B.

FIGS. 2B and 2C are schematic top views of the inner valve of FIG. 2A, shown in a first configuration and a second configuration, respectively.

FIGS. 3-5 are front, bottom, and top views, respectively, of a prosthetic heart valve .

FIGS. 6A and 6B are schematic illustrations of a portion of a prosthetic heart valve, shown in a first configuration and a second configuration, respectively.

FIGS. 6C and 6D are schematic illustrations of the portion of the prosthetic heart valve of FIGS. 6A and 6B, respectively, shown disposed within a delivery sheath.

FIGS. 7A and 7B are schematic illustrations of the portion of a prosthetic heart valve of FIGS. 6A and 6B, shown in the first configuration and the second configuration, respectively.

FIG. 8A is a front view of a prosthetic heart valve according to an embodiment of the invention shown in a first configuration.

FIG. 8B is a front view of the prosthetic heart valve of FIG. 8A, shown in a second configuration.

FIG. 9A is a front view of a prosthetic heart valve according to another embodiment of the invention, shown in a first configuration.

FIG. 9B is an enlarged view of encircled portion A of the prosthetic heart valve of FIG. 9A.

FIG. 9C is a front view of the prosthetic heart valve of FIG. 9A, shown in a second configuration.

FIG. 10A is a cross-sectional side view of a prosthetic heart valve, according to another embodiment of the invention.

FIG. 10B is an enlarged view of encircled area A in FIG. 10A.

FIG. 10C is a perspective view of the prosthetic heart valve of FIG. 10A.

FIG. 10D is a perspective view of a prosthetic heart valve, according to another embodiment of the invention. .

*Detailed Description*

**[0009]** Prosthetic heart valves are described herein that include an outer frame coupled to an inner frame. The outer frame and the inner frame define between them an annular space, and a pocket closure bounds the annular space to form a pocket in which thrombus can form and be retained. According to the invention, a prosthetic heart valve includes an outer frame coupled to an inner frame such that the outer frame can be moved between a first position relative to the inner frame and a second position relative to the inner frame in which the outer frame is inverted relative to the inner frame. In an embodiment according to the invention, the pocket closure can include a stretchable pocket covering that can move from a first position in which the pocket covering has a first length when the outer frame is in the first position relative to the inner frame and a second position in which the pocket covering has a second length greater than the first length when the outer frame is in the second position relative to the inner frame.

**[0010]** In some embodiments, prosthetic heart valves described herein can be configured to be moved to an inverted configuration for delivery of the prosthetic valve to within a heart of a patient. According to the invention, a prosthetic valve includes an outer frame that can be inverted relative to an inner frame when the prosthetic valve is in a biased expanded configuration. The prosthetic mitral valve can be formed with, for example, a shape-memory material. After inverting the outer frame, the prosthetic valve can be inserted into a lumen of a delivery sheath such that the prosthetic valve is moved to a collapsed configuration.

**[0011]** The delivery sheath can be used to deliver an inverted prosthetic valve as described herein to within a patient's heart using a variety of different delivery approaches for delivering a prosthetic heart valve (e.g., prosthetic mitral valve) where the inverted prosthetic valve would enter the heart through the atrium of the heart. For example, the prosthetic valves described herein can be delivered using a transfemoral delivery approach as described in International Application No. PCT/US15/14572 (the '572 PCT application) published as WO2015120122 A2, above or via a transatrial approach, such as described in U.S. Provisional Patent Application Serial No. 62/220,704, entitled "Apparatus and Methods for Transatrial Delivery of Prosthetic Mitral Valve," filed September 18, 2015 ("the '704 provisional application"), and described in U.S. Patent Application No. 15/265,221 filed September 14, 2016 (the '221 application"), published as US2017079790 A1.

**[0012]** In another example, an inverted valve as described herein could be delivered via a transjugular approach, via the right atrium and through the atrial septum and into the left atrium, as described in the '221 application. The prosthetic valves described herein can also be delivered apically if desired. After the delivery sheath has been disposed within the left atrium of the heart, the prosthetic mitral valve is moved distally out of the delivery sheath such that the inverted outer frame reverts and the prosthetic valve assumes its biased expanded configuration. The prosthetic mitral valve can then be positioned within a mitral annulus of the heart.

**[0013]** A schematic representation of a prosthetic heart valve 100 is shown in FIGS. 1A and 1B. Prosthetic heart valve 100 (also referred to as "prosthetic valve" or "valve") is designed to replace a damaged or diseased native heart valve such as a mitral valve. Valve 100 includes an outer frame assembly 110 and an inner valve assembly 140 that is coupled to the outer frame assembly.

**[0014]** Although not separately shown in the schematic illustration of outer frame assembly 110 in FIGS. 1A and 1B, outer fame assembly 110 may be formed of an outer frame 120, and can be covered on all or a portion of its outer face with an outer covering (not shown), and covered on all or a portion of its inner face by an inner covering (not shown). An embodiment of a prosthetic valve showing the inner and outer coverings is described below with respect to FIGS. 3-5. In some embodiments, the outer frame assembly 110 can include a covering on only an outer face or only an inner face of the outer frame 120. In some embodiments, there can be more than one layer of covering on the inner face and/or the outer face of the outer frame 120. The inner and outer coverings of the outer frame assembly 110 can completely cover the inner face and/or outer face of the outer frame 120 or can partially cover the inner face and/or the outer face of the outer frame 120. In some embodiments, the outer frame assembly 110 may not include a covering on the inner face or the outer face of the outer frame 120. For example, in some embodiments, the outer frame assembly 110 can include no material or covering on an inner face of the outer frame 120 and two layers or coverings disposed on an outer face of the outer frame 120. In such an embodiment, a first layer or covering can be, for ex-

ample, a tissue that fully covers the outer face of the outer frame 120 and the outermost layer or covering can be a thin polyester that covers only a portion of the outer frame 120. For example, the outermost covering can cover one or two rows of cells of a cuff portion of the outer frame 120.

**[0015]** Outer frame 120 can provide several functions for prosthetic heart valve 100, including serving as the primary structure, as an anchoring mechanism and/or an attachment point for a separate anchoring mechanism to anchor the valve to the native heart valve apparatus, a support to carry inner valve assembly 140, and/or a seal to inhibit paravalvular leakage between prosthetic heart valve 100 and the native heart valve apparatus.

**[0016]** Outer frame 120 is preferably formed so that it can be deformed (compressed and/or expanded) and, when released, return to its original (undeformed) shape. To achieve this, outer frame 120 is preferably formed of materials, such as metals or plastics, that have shape memory properties. With regards to metals, Nitinol® has been found to be especially useful since it can be processed to be austenitic, martensitic or super elastic. Other shape memory alloys, such as Cu-Zn-Al-Ni alloys, and Cu-Al-Ni alloys, may be used.

**[0017]** Outer frame 120 is preferably formed from a laser cut, thin-walled tube of Nitinol®. The laser cuts form regular cutouts in the thin Nitinol® tube. The tube can be expanded radially, placed on a mold or mandrel of the desired shape, heated to the martensitic temperature, and quenched. The treatment of the frame in this manner will form an open lattice frame structure, and may have a flared end or cuff at the atrium end portion 116 of outer frame 120. Outer frame 120 thus has shape memory properties and will readily revert to the memory shape at the calibrated temperature. Alternatively, outer frame 120 may be constructed from braided wire or other suitable material.

**[0018]** Inner valve assembly 140 is shown schematically in more detail in FIGS. 2A-2C. Inner valve assembly 140 can include an inner frame 150, an outer covering 160, and leaflets 170. In the simplified form shown schematically in FIG. 2A, inner frame 150 includes six axial posts or frame members that support outer covering 160 and leaflets 170. Leaflets 170 are attached along three of the posts, shown as commissure posts 152 in FIG. 2A, and outer covering 160 is attached to the other three posts, 154 in FIG. 2A, and optionally to commissure posts 152. The outer covering 160 can be attached to an inner face of the inner frame 150 or to an outer face of the inner frame 150. As shown schematically in FIG. 2A, each of outer covering 160 and leaflets 170 are formed of approximately rectangular sheets of material, which are joined together at their upper, or atrium end. The lower, ventricle end of outer covering 160 may be joined to the inner covering (not shown) of outer frame assembly 110 (not shown in FIG. 2A), and the lower, ventricle end of leaflets 170 may form free edges, though coupled to the lower ends of commissure posts 152. In some embodiments, the covering 160 and leaflets 170 can be formed from a single rectangular sheet of material, then folded over and trimmed to the shape of the inner frame, staying connected at the top of the inner frame where the material is folded over. In some embodiments, the covering 160 and/or the leaflets 170 can be formed from material having a shape other than rectangular, such as from a semicircular piece of material, or can be laser cut to the shape of the inner frame.

**[0019]** As shown in FIGS. 2B and 2C, leaflets 170 are movable between a first or open configuration (FIG. 2B), and a second or closed configuration (FIG. 2C) in which the leaflets 170 coapt, or meet in sealing abutment.

**[0020]** At the lower, or ventricle end, leaflets 170 may have a smaller outer perimeter than outer covering 160. Thus, the free lower edges of the leaflets 170, between commissure posts 152 (each portion of leaflets 170 between adjacent commissure posts being referred to as a "belly" of leaflets 170) are spaced radially from the lower edge of outer covering 160. This radial spacing facilitates movement of the leaflets from the open position in FIG. 2B to the closed position in FIG. 2C, as the counter flow of blood from the ventricle to the atrium during systole can catch the free edges of the bellies and push the leaflets closed.

**[0021]** The outer covering and the inner covering of outer frame assembly 110, outer covering 160 and leaflets 170 may be formed of any suitable material, or combination of materials. In some embodiments, the outer covering and the inner covering of outer frame assembly 110, outer covering 160 and leaflets 170 may be formed of a tissue. In some embodiments, the tissue is optionally a biological tissue, such as a chemically stabilized tissue from a heart valve of an animal, such as a pig, or pericardial tissue of an animal, such as cow (bovine pericardium) or sheep (ovine pericardium) or pig (porcine pericardium) or horse (equine pericardium). Examples of suitable tissue include that used in the products Duraguard®, Peri-Guard®, and Vascu-Guard®, all products currently used in surgical procedures, and which are marketed as being harvested generally from cattle less than 30 months old. Alternatively, valve leaflets 170 may optionally be made from pericardial tissue or small intestine submucosal tissue.

**[0022]** Synthetic materials, such as polyurethane or polytetrafluoroethylene, may also be used for valve leaflets 170. Where a thin, durable synthetic material is contemplated, e.g. for the outer covering or the inner covering of outer frame assembly 110, synthetic polymer materials such as, for example, expanded polytetrafluoroethylene or polyester may optionally be used. Other suitable materials may optionally include thermoplastic polycarbonate urethane, polyether urethane, segmented polyether urethane, silicone polyether urethane, silicone-polycarbonate urethane, and ultra-high molecular weight polyethylene. Additional biocompatible polymers may optionally include polyolefins, elastomers, polyethyleneglycols, polyethersulphones, polysulphones, polyvinylpyrrolidones, polyvinylchlorides, other fluoropoly-

mers, silicone polyesters, siloxane polymers and/or oligomers, and/or polylactones, and block co-polymers using the same.

**[0023]** In another embodiment, valve leaflets 170 may optionally have a surface that has been treated with (or reacted with) an anti-coagulant, such as, without limitation, immobilized heparin. Such currently available heparinized polymers are known and available to a person of ordinary skill in the art.

**[0024]** As shown in FIGS. 1A, 1B, and 2A, inner valve assembly 140 may be substantially cylindrical, and outer frame assembly 110 may be tapered, extending from a smaller diameter (slightly larger than the outer diameter of inner valve assembly 140) at a lower, ventricle portion 112 (where it is coupled to inner valve assembly 140) to a larger diameter, atrium portion 116, with an intermediate diameter, annulus portion 114 between the atrium and ventricle portions, 112 and 116, respectively.

**[0025]** A tapered annular space or pocket 185 (also referred to herein as "atrial pocket") is thus formed between the outer surface of inner valve assembly 140 and the inner surface of outer frame assembly 110, open to the atrium end of valve assembly 100. When valve assembly 100 is disposed in the annulus of a native heart valve, blood from the atrium can move in and out of pocket 185. The blood can clot, forming thrombus. To enhance clotting, ingrowth of tissue into the surfaces of valve 100, and produce other benefits, the pocket can be covered, or enclosed, by a pocket closure 180 (also referred to as an "atrial pocket closure").

**[0026]** Pocket closure 180 can be formed at least in part of any suitable material that is sufficiently porous to allow blood, including particularly red blood cells, to enter pocket 185, but is not so porous as to allow undesirably large thrombi to leave the pocket 185. For example, pocket closure 180 may be formed at least in part from a woven or knit polyester fabric with apertures less than 160 $\mu$, and preferably between 90 $\mu$ and 120 $\mu$. In some embodiments, the pocket closure 180 can be formed at least in part from a braided Nitinol material that has a desired porosity. In some embodiments, the pocket closure 180 can be formed at least in part from a braided tubular Nitinol material. It is not necessary for the entirety of pocket closure 180 to be formed of the same material, with the same porosity. For example, some portions of pocket closure 180 may be formed of a less porous, or blood impermeable, material and other portions formed of material of the porosity range noted above. It is also contemplated that a portion of the outer frame assembly 110 or the inner valve assembly 140 may be formed with an aperture that communicates with pocket 180, covered by a closure formed of material having the desired porosity, thus providing another path by which blood may enter, but thrombi are prevented from leaving, atrial pocket 185.

**[0027]** The outer surface of inner valve assembly 110, and/or the inner surface of outer frame assembly 140, need not by circular in cross-section as shown schematically in FIGS. 1A and 1B, but may be of non-constant radius at a given location along the central axis of valve 100. Thus, pocket 185 may not be of constant cross-section, and may not be continuous, but rather may be formed in two or more fluidically isolated, partially annular volumes. Similarly, pocket closure 180 need not be shaped as a ring with constant width as shown schematically in FIGS. 1A and 1B, but rather can be a continuous ring of varying with, a more complicated continuous shape, or may be formed in multiple, discrete sections. In some embodiments, the pocket closure 180 can be formed as a tubular member defining an interior region.

**[0028]** Pocket closure 180 serves to trap and/or slow the flow of blood within pocket 185, which can increase formation and retention of thrombus in pocket 185. It also promotes active in-growth of native tissue into the several coverings of prosthetic heart valve 100, further stabilizing valve 100 in the native heart valve. The material forming the outer covering of inner valve assembly 140 can also be hardened or stiffened, providing better support for leaflets 170. Also, a mass of thrombus filling pocket 185 can serve as potting for inner valve assembly 140, further stabilizing the valve assembly. Greater stability for inner valve assembly 140 can provide more reliable coaption of valve leaflets 170, and thus more effective performance. The mass of thrombus can also stabilize the outer frame assembly 110 after it has been installed in, and flexibly conformed to, the native valve apparatus. This can provide a more effective seal between prosthetic heart valve 100 and the native valve apparatus, and reduce perivalvular leakage.

**[0029]** FIGS. 3-5 are front, bottom, and top views, respectively, of a prosthetic heart valve 200 according to an embodiment. Prosthetic heart valve 200 (also referred to herein as "valve" or "prosthetic valve") is designed to replace a damaged or diseased native heart valve such as a mitral valve. Valve 200 includes an outer frame assembly 210 and an inner valve assembly 240 coupled to the outer frame assembly 210.

**[0030]** As shown, outer frame assembly 210 includes an outer frame 220, covered on all or a portion of its outer face with an outer covering 230, and covered on all or a portion of its inner face by an inner covering 232. Outer frame 220 can provide several functions for prosthetic heart valve 200, including serving as the primary structure, as an anchoring mechanism and/or an attachment point for a separate anchoring mechanism to anchor the valve to the native heart valve apparatus, a support to carry inner valve assembly 240, and/or a seal to inhibit paravalvular leakage between prosthetic heart valve 200 and the native heart valve apparatus.

**[0031]** Outer frame 220 has a biased expanded configuration and can be manipulated and/or deformed (e.g., compressed and/or constrained) and, when released, return to its original unconstrained shape. To achieve this, outer frame 220 can be formed of materials, such as metals or plastics, that have shape memory properties. With regards to metals, Nitinol® has been found to be especially useful since it can be processed to be austenitic,

martensitic or super elastic. Other shape memory alloys, such as Cu-Zn-Al-Ni alloys, and Cu-Al-Ni alloys, may also be used.

**[0032]** As best shown in FIG. 3, outer frame assembly 210 has an upper end (e.g., at the atrium portion 216), a lower end (e.g., at. the ventricle portion 212), and a medial portion (e.g., at the annulus portion 214) therebetween. The upper end or atrium portion 216 (also referred to as "free end portion" or "open end portion") defines an open end portion of the outer frame assembly 210. The medial or annulus portion 214 of the outer frame assembly 210 has a perimeter that is configured (e.g., sized, shaped) to fit into an annulus of a native atrioventricular valve. The upper end of the outer frame assembly 210 has a perimeter that is larger than the perimeter of the medial portion. In some embodiments, the perimeter of the upper end of the outer frame assembly 210 has a perimeter that is substantially larger than the perimeter of the medial portion. As shown best in FIG. 5, the upper end and the medial portion of the outer frame assembly 210 has a D-shaped cross-section. In this manner, the outer frame assembly 210 promotes a suitable fit into the annulus of the native atrioventricular valve.

**[0033]** Inner valve assembly 240 includes an inner frame 250, an outer covering 260, and leaflets 270. As shown, the inner valve assembly 240 includes an upper portion having a periphery formed with multiple arches. The inner frame 250 includes six axial posts or frame members that support outer covering 260 and leaflets 270. Leaflets 270 are attached along three of the posts, shown as commissure posts 252 (best illustrated in FIG. 4), and outer covering 260 is attached to the other three posts, 254 (best illustrated in FIG. 4), and optionally to commissure posts 252. Each of outer covering 260 and leaflets 270 can be formed as described above for outer covering 160 and leaflets 170. For example, each of outer covering 260 and leaflets 270 can be formed of approximately rectangular sheets of material, which are joined together at their upper, or atrium end. The lower, ventricle end of outer covering 260 may be joined to inner covering 232 of outer frame assembly 210, and the lower, ventricle end of leaflets 270 may form free edges 275, though coupled to the lower ends of commissure posts 252.

**[0034]** Although inner valve assembly 240 is shown as having three leaflets, in other embodiments, an inner valve assembly can include any suitable number of leaflets. The leaflets 270 are movable between an open configuration and a closed configuration in which the leaflets 270 coapt, or meet in a sealing abutment.

**[0035]** Outer covering 230 of the outer frame assembly 210 and inner covering 232 of outer frame assembly 210, outer covering 260 of the inner valve assembly 240 and leaflets 270 of the inner valve assembly 240 may be formed of any suitable material, or combination of materials, such as those discussed above for valve 100. In this embodiment, the inner covering 232 of the outer frame assembly 210, the outer covering 260 of the inner valve assembly 240, and the leaflets 270 of the inner valve assembly 240 are formed, at least in part, of porcine pericardium. Moreover, in this embodiment, the outer covering 230 of the outer frame assembly 210 is formed, at least in part, of polyester.

**[0036]** Prosthetic valve 200 also defines a tapered annular space or pocket (not shown) formed between the outer surface of inner valve assembly 240 and the inner surface of outer frame assembly 210, open to the atrium end of valve assembly 200. As shown, a pocket closure or covering 280 (the pocket being disposed below pocket closure 280 in the top view of FIG. 5) is coupled along the periphery of the upper end of the inner valve assembly 240 and also to the outer valve assembly 210. In some embodiments, the pocket closure 280, or a portion thereof, can be coupled along any suitable portion of the inner valve assembly 240.

**[0037]** As discussed above, pocket closure 280 can be formed at least in part of any suitable material that is sufficiently porous to allow blood, including particularly red blood cells, to enter the pocket, but is not so porous as to allow undesirably large thrombi to leave the pocket. In this embodiment, pocket closure 280 is formed entirely of knit polyester (i.e., PET warp knit fabric) having apertures of about 90-120 microns. In some embodiments, a pocket closure can include apertures less than about 160 microns.

**[0038]** As previously described, in some embodiments, a prosthetic heart valve, such as a prosthetic mitral valve, can be configured to be moved to an inverted configuration for delivery of the prosthetic valve to within a heart of a patient. According to the invention, the outer frame can be moved or inverted relative to the inner frame of the valve. After inverting the outer frame, the prosthetic valve can be inserted into a lumen of a delivery sheath such that the prosthetic valve is moved to a collapsed configuration for delivery of the valve o the heart. FIGS. 6A-6D and FIGS.7A and 7B illustrate schematically an embodiment of a prosthetic valve that can be moved between a biased expanded configuration for use and an inverted configuration for delivery to a heart.

**[0039]** FIGS. 6A and 6B are schematic illustrations of a portion of a prosthetic heart valve 300, according to an embodiment, shown in a first configuration and a second configuration respectively, and FIGS. 6C and 6D illustrate the portions of the prosthetic heart valve 300 of FIGS. 6A and 6B, respectively, shown disposed within a lumen of a delivery sheath 326. FIGS. 7A and 7B illustrate a portion of the prosthetic heart valve 300 of FIGS. 6A and 6B, respectively, and show length dimensions for the prosthetic heart valve in each of the first configuration and the second configuration. The prosthetic heart valve 300 (also referred to herein as "prosthetic valve" or "valve") can be, for example, a prosthetic mitral valve. The valve 300 includes an outer frame 320 and an inner frame 350. The outer frame 320 and the inner frame 350 are each formed as a tubular structure. The outer frame 320 and the inner frame 350 can be coupled together at multiple coupling joints 346 disposed about a perimeter

of the inner frame 350 and a perimeter of the outer frame 320 as described in more detail below. The valve 300 can also include other features, such as those described above with respect to FIGS. 1-5. For example, the valve 300 can include an outer frame assembly, including the outer frame 320, and an inner valve assembly that includes the inner frame 350, that can be formed or configured the same as or similar to the outer frame assemblies and inner valve assemblies described above with respect to FIGS. 1-5. For illustration purposes, only the inner frame 350 and the outer frame 320 are discussed with respect to FIGS. 6A-7B. The various characteristics and features of valve 300 described with respect to FIGS. 6A-7B can apply to any of the prosthetic valves described here.

**[0040]** The outer frame 320 is configured to have a biased expanded or undeformed shape and can be manipulated and/or deformed (e.g., compressed or constrained) and, when released, return to its original (expanded or undeformed) shape. For example, the outer frame 320 can be formed of materials, such as metals or plastics, that have shape memory properties. With regards to metals, Nitinol® has been found to be especially useful since it can be processed to be austenitic, martensitic or super elastic. Other shape memory alloys, such as Cu-Zn-Al-Ni alloys, and Cu-Al-Ni alloys, may also be used. The inner frame 350 can be formed from a laser-cut tube of Nitinol®. The inner frame 350 can also have a biased expanded or undeformed shape and can be manipulated and/or deformed (e.g., compressed and/or constrained) and, when released, return to its original (expanded or undeformed) shape. Further details regarding the inner frame 350 and the outer frame 320 are described below and with respect to valve 200 and FIGS. 3-5.

**[0041]** The valve 300 can be delivered and deployed within a left atrium of a heart using a variety of different delivery approaches including, for example, a transfemoral delivery approach, as described in the '572 PCT application, or a transatrial approach, as described in the '704 provisional application and the '221 application, or a transjugular approach as described, for example, in the '221 application. As described above, in some situations, such as when delivering a prosthetic valve to the heart via a transfemoral, transjugular or transatrial approach, because of the smaller size of the lumen of the delivery sheath, the size of the prosthetic valve during delivery should be sized accordingly. Thus, it is desirable to have a prosthetic valve that can be reconfigured between a biased expanded configuration for implantation in the heart (e.g., within a native mitral annulus) and a delivery configuration that has a smaller outer perimeter or profile to allow for delivery within the lumen of the delivery sheath. The prosthetic valve 300 and the embodiments of a prosthetic valve described herein can be constructed and formed to achieve these desired functions and characteristics.

**[0042]** More specifically, the valve 300 can have a biased expanded configuration (as shown in FIGS. 6A and 7A), an inverted configuration (as shown in FIGS. 6B and 7B), and a compressed or collapsed configuration (as shown in FIGS. 6C and 6D). The expanded configuration allows the valve 300 to function when implanted within the heart. The valve 300 can be moved to the inverted configuration and the compressed or collapsed configuration for delivery of the valve 300 to the heart of a patient.

**[0043]** To enable the valve 300 to be moved to the inverted configuration, the outer frame 320 can be coupled to the inner frame 350 in such a manner to allow the outer frame 320 to move relative to the inner frame 350. More specifically, the coupling joints 346 can couple the outer frame 320 to the inner frame 350 in such a manner to allow the outer frame 320 to be moved relative to the inner frame 350. For example, in some embodiments, the coupling joints 346 can be configured to allow the outer frame 320 to rotate about the coupling joint 346 relative to the inner frame 350. In some embodiments, coupling joints can provide a pivotal coupling between the outer frame 320 and the inner frame 350. In some embodiments, the coupling joints can provide a flexible attachment between the outer frame 320 and the inner frame 350. The coupling joints 346 can be a variety of different types and configurations as described herein with reference to the various embodiments of a prosthetic valve. For example, the coupling joints 146 can include a living hinge, a flexible member, sutures, a suture wrapped through an opening, a pin or tab inserted through an opening or any combinations thereof.

**[0044]** To move the valve 300 from the expanded configuration (FIG. 6A) to the inverted configuration (FIG. 6B), the outer frame 320 is moved to a prolapsed or inverted configuration relative to the inner frame 350, as shown in FIGS. 6B, 6D and 7B, by moving (e.g., rotating, pivoting, flexing) the outer frame 320 about the coupling joints 346. The elastic or superelastic structure of outer frame 320 of valve 300 also allows the outer frame 320 to be moved to, and disposed in, the prolapsed or inverted configuration relative to the inner frame 350. To move the outer frame 320 to the inverted configuration relative to the inner frame 350, the outer frame 320 is folded or inverted distally (to the right in FIG. 6B) relative to the inner frame 350 via the coupling joints 346. As shown in FIGS. 6A and 7A, the outer frame 320 is in a first position relative to the inner frame 350 prior to being inverted in which an open or free end portion 316 (also referred to the atrium portion 316 of the outer frame 320) is disposed proximally or to the left of the coupling joints 346 and in the same direction as a free end portion 347 (also referred to as a second end portion of the inner frame) of the inner frame 350. When the outer frame 320 is moved to an inverted configuration (i.e., second positon relative to the inner frame 350), the free end portion 316 is disposed distally of the coupling joints 346 (or to the right in FIGS. 6B and 7B) and in an opposite direction as the free end portion 347 of the inner frame 350. Said another way, when the valve 300 is in a biased expanded configuration

(e.g., FIG. 6A), the coupling joints 346 are disposed between a first end portion 344 (also referred to as a tether coupling portion) of the inner frame 350 and the free end portion 316 of the outer frame 320. When the valve 300 is in the inverted configuration (e.g., FIG. 6B) (i.e., the outer frame 320 has been moved to an inverted configuration or position), the coupling joints 346 are disposed between the free end portion or second end portion 347 of the inner frame 350 and the free end portion 316 of the outer frame 320.

**[0045]** When in the inverted configuration, an overall length of the valve 300 is increased, but a length of the inner frame 350 and a length of the outer frame 320 remains the same (or substantially the same). For example, as shown in FIGS. 7A and 7B an overall length L1 of the valve 300 in the biased expanded configuration (prior to being inverted as shown in FIG. 7A) is less than the overall length L2 of the valve 300 when in the inverted configuration (FIG. 7B). A length Li of the inner frame 350 and a length $L_O$ of the outer frame 320 is substantially the same (or the same) when the valve 300 is in both the biased expanded configuration and the inverted configuration. In addition, in some instances, depending on the specific configuration of the outer frame, an overall outer perimeter or outer diameter of the valve 300 can be smaller when the valve 300 is in the inverted configuration.

**[0046]** With the valve 300 in the inverted configuration, the valve 300 can be placed within a lumen of the delivery sheath 326 for delivery of the valve 300 to the left atrium of the heart, as shown in FIG. 6D. When placed within the lumen of the delivery sheath 326, the valve 300 is moved to the collapsed or compressed configuration in which the outer diameter or outer perimeter of the valve 300 is reduced. Because the valve 300 is in the inverted configuration, the valve 300 is able to be placed within a smaller delivery sheath 326 than would otherwise be possible. For example, for comparison purposes, FIG. 6C illustrates the valve 300 placed within a lumen of a delivery sheath 326' where the valve 300 has not been moved to an inverted configuration prior to being disposed within the delivery sheath 326'. As shown in FIG. 6C, an outer diameter of the valve 300 is reduced, but not to as small of a diameter as for the valve 100 when placed in a delivery sheath 326 when in the inverted configuration. Thus, in FIG. 6C, the valve 300 has an overall outer perimeter or outer diameter D1 and in FIG. 6D, the valve 300 has an overall outer perimeter or outer diameter D2, which is less than D1.

**[0047]** Thus, by disposing the outer frame 320 in the inverted configuration, the valve 300 can be collapsed into a smaller overall diameter, i.e. placed in a smaller diameter delivery sheath 326, than would be possible if the valve 300 were merely collapsed radially. This is because when the valve is in the biased expanded configuration, the inner frame 350 is nested within an interior of the outer frame 320, and thus the outer frame 320 must be collapsed around the inner frame 350. In some embodiments, the inner frame 350 and the outer frame are disposed concentrically. Whereas in the inverted configuration, the inner frame 350 and the outer frame 320 are arranged axially with respect to each other (i.e., the inner frame is not nested within the outer frame 350), such that the outer frame 320 can be collapsed without needing to accommodate all of the structure of the inner frame 350 inside it. In other words, with the inner frame 350 disposed mostly inside or nested within the outer frame 320, the layers or bulk of the frame structures cannot be compressed to as small a diameter. In addition, if the frames are nested, the structure is less flexible, and therefore, more force is needed to bend the valve, e.g. to pass through tortuous vasculature or to make tight turn in the left atrium after passing through the atrial septum to be properly oriented for insertion into the mitral valve annulus.

**[0048]** FIGS. 8A and 8B illustrate another embodiment of a prosthetic heart valve that can be delivered and deployed within a left atrium of a heart using a variety of different delivery approaches and which can be moved between an expanded configuration and an inverted configuration as described above for valve 300. The prosthetic heart valve 400 (also referred to herein as "prosthetic valve" or "valve") can be, for example, a prosthetic mitral valve. The valve 400 includes an outer frame assembly including an outer frame 420 and an inner valve assembly including an inner frame 450. The outer frame 420 and the inner frame 450 are each formed as a tubular structure. The valve 400 can also include other features, such as those described above with respect to FIGS. 1A-7D. For illustration purposes, only the inner frame 450 and the outer frame 420 are discussed with respect to FIGS. 8A-8B. It should be understood that the various characteristics and features of the valves described above with respect to FIGS. 1A-7D can apply to valve 400.

**[0049]** The outer frame 420 and the inner frame 450 can be coupled together at multiple coupling joints 446 disposed about a perimeter of the inner frame 450 and a perimeter of the outer frame 420 as described above for valve 300. The coupling joints 446 can allow the outer frame 420 to be moved relative to the inner frame 450 as described above for valve 300. For example, the outer frame 420 can be moved between a first position (FIG. 8A) relative to the inner frame 450 to a second position (FIG. 8B) relative to the inner frame 450. In the first position, an open free end portion 416 of the outer frame 420 is disposed in the same direction as an open free end portion 447 of the inner frame 450 (see FIG. 8A). In the second position, the outer frame 420 is inverted relative to the inner frame 450 such that the free end portion 416 of the outer frame 420 is now disposed in an opposite direction as the free end portion 447 of the inner frame 450 (see FIG. 8B).

**[0050]** As described above for valves 100 and 200, a tapered annular space or pocket 485 (also referred to as "atrial pocket") is formed between an outer surface of the inner valve assembly and an inner surface of the outer

frame assembly, open to an atrium end of valve 400. When valve 400 is disposed in the annulus of a native heart valve, blood from the atrium can move in and out of pocket 485. The blood can clot, forming thrombus. To enhance clotting, ingrowth of tissue into the surfaces of valve 400, and produce other benefits, the pocket 485 is covered, or enclosed, by a pocket closure 480 (also referred to as an "atrial pocket closure"). The pocket closure 480 is coupled about a perimeter of the inner frame 450 and a perimeter of the outer frame 420 so as to close-out the pocket 485 at the atrial end of the valve 400. As shown in FIGS. 8A and 8B the pocket closure 480 is coupled to the inner frame 450 at coupling portion 482 and to outer frame 420 at coupling portion 483. The pocket closure 480 can be formed of one continuous segment or portion of material or can be formed with two or more portions or segments that are coupled together. For example, in some embodiments, the pocket closure 480 can be formed of three portions or segments that are sewn together with sutures or another suitable coupling method.

**[0051]** As described above, pocket closure 480 can be formed at least in part of any suitable material that is sufficiently porous to allow blood, including particularly red blood cells, to enter the pocket 485, but is not so porous as to allow undesirably large thrombi to leave the pocket 485. For example, pocket closure 480 may be formed at least in part from a material with apertures less than 160 $\mu$, and preferably between 90 $\mu$ and 120 $\mu$. In this embodiment, the pocket closure 480 can be formed at least in part from a braided Nitinol material (or a braided tubular Nitinol material) that has the desired porosity. The braided Nitinol material also provides a desired stretchability, flexibility or deformability to accommodate movement of the outer frame 420 between the first positon relative to the inner frame 450 and the second inverted position relative to the inner frame 450. For example, the braided Nitinol material can have shape memory properties that allow the pocket closure 480 to be deformed and/or stretched and then revert back to an original shape or configuration when released.

**[0052]** As shown in FIG. 8A, when the outer frame 420 is in the first position relative to the inner frame 450, the pocket closure 480 is disposed in a first configuration. As shown in FIG. 8B, when the outer frame 420 is in the second position (i.e., inverted) relative to the inner frame 450, the pocket closure 480 is disposed in a second configuration. More specifically, when the outer frame 420 is moved to the second position in which the outer frame 420 is inverted relative to the inner frame 420, the material and structure of the pocket closure 480 enables the pocket closure 480 to stretch with the outer frame 420 as shown in FIG. 8B. In other words, as shown in FIG. 8B, the pocket closure 480 is stretched or elongated between where it is coupled to the inner frame (i.e., coupling portion 482) and where it is coupled to the outer frame (i.e., coupling portion 483) to a length greater than when the outer frame 420 is in the first positon as shown in FIG. 8A. When the outer frame 420 is moved back to the first position relative to the inner frame 450, the pocket closure 480 can assume its first configuration as shown in FIG. 8A.

**[0053]** FIGS. 9A and 9B illustrate another embodiment of a prosthetic heart valve that includes a pocket closure that can accommodate the valve being moved between an expanded configuration and an inverted configuration for delivery and deployment of the valve within a left atrium of a heart. The prosthetic heart valve 500 (also referred to herein as "prosthetic valve" or "valve") can be, for example, a prosthetic mitral valve. The valve 500 includes an outer valve assembly including an outer frame 520 and an inner valve assembly including an inner frame 550. The outer frame 520 and the inner frame 550 are each formed as a tubular structure. The valve 500 can also include other features, such as those described above with respect to FIGS. 1A-7D. For illustration purposes, only the inner frame 550 and the outer frame 520 are discussed with respect to FIGS. 8A-8B. It should be understood that the various characteristics and features of the valves described above with respect to FIGS. 1A-7D can apply to valve 500.

**[0054]** As with the previous embodiments, the outer frame 520 and the inner frame 550 can be coupled together at multiple coupling joints 546 disposed about a perimeter of the inner frame 550 and a perimeter of the outer frame 520 as described above for valve 300. The coupling joints 546 can allow the outer frame 520 to be moved relative to the inner frame 550 as described above for valve 300. For example, the outer frame 520 can be moved between a first position (FIG. 9A) relative to the inner frame 550 to a second position (FIG. 9B) relative to the inner frame 550. In the first position, an open free end portion 516 of the outer frame 520 is disposed in the same direction as an open free end portion 547 of the inner frame 550 (see FIG. 9A). In the second position, the outer frame 520 is inverted relative to the inner frame 550 such that the free end portion 516 of the outer frame 520 is now disposed in an opposite direction as the free end portion 547 of the inner frame 550 (see FIG. 9B).

**[0055]** As described above for valves 100 and 200, a tapered annular space or pocket 585 (also referred to as "atrial pocket") is formed between an outer surface of the inner valve assembly and an inner surface of the outer frame assembly, open to an atrium end of valve 500. When valve 500 is disposed in the annulus of a native heart valve, blood from the atrium can move in and out of pocket 585. The blood can clot, forming thrombus. To enhance clotting, ingrowth of tissue into the surfaces of valve 500, and produce other benefits, the pocket 585 is covered, or enclosed, by a pocket closure 580 (also referred to as an "atrial pocket closure").

**[0056]** In this embodiment, the pocket closure 580 includes a first portion 584 coupled to a second portion 586. As shown in the detail view of FIG. 9B, the first portion 584 includes a first end coupled to the outer frame 520 at a coupling joint 587, and a second end coupled

to the second portion 586 at a coupling joint 588. The second portion 586 has a first end coupled to the first portion 584 at the coupling joint 588 and a second end coupled to the outer frame 520 at a coupling joint 589. Thus, in this embodiment, the pocket closure 580 is coupled only to the outer frame 520. The pocket closure 580 can close-out the pocket at the atrial end of the valve 500. The first portion 584 and the second portion 586 of the pocket closure 580 can each be formed as one continuous segment or portion of material or can be formed with two or more portions or segments that are coupled together with for example, sutures or another suitable coupling method.

**[0057]** As described above, pocket closure 580 can be formed at least in pail of any suitable material that is sufficiently porous to allow blood, including particularly red blood cells, to enter the pocket 585, but is not so porous as to allow undesirably large thrombi to leave the pocket 585. For example, pocket closure 580 may be formed at least in part from a material with apertures less than 160 μ, and preferably between 90 μ and 120 μ. In this embodiment, the first portion 584 of pocket closure 580 can be formed at least in part from a woven or knit polyester fabric with apertures less than 160 μ, and preferably between 90 μ and 120 μ. The second portion 586 of pocket closure 580 can be formed with a tubular braided Nitinol material as described above for valve 400 that can provide a desired stretchability or flexibility or deformability to accommodate the outer frame 520 moving between the first positon relative to the inner frame 550 and the second inverted position relative to the inner frame 550.

**[0058]** As shown in FIG. 9A, when the outer frame 520 is in the first position relative to the inner frame 550, the pocket closure 580 is disposed in a first configuration. As shown in FIG. 9B, when the outer frame 520 is in the second position (i.e., inverted) relative to the inner frame 550, the pocket closure 580 is disposed in a second configuration. More specifically, when the outer frame 520 is moved to the second position in which the outer frame 520 is inverted relative to the inner frame 520, the material and structure of the second portion 586 of the pocket closure 580 enables the pocket closure 580 to stretch with the outer frame 520 as shown in FIG. 9B. In other words, as shown in FIG. 9B, the second portion 586 of pocket closure 580 can stretch or elongate between where it is coupled to the first portion 584 of the pocket closure 580 (i.e., coupling joint 588) and where it is coupled to the outer frame 520 (i.e., coupling portion 589) to a length greater than when the outer frame 520 is in the first positon as shown in FIG. 9A. The first portion 584 of pocket closure 580 does not stretch when the outer frame 520 is moved to the second position (i.e., inverted) relative to the inner frame 550. When the outer frame 520 is moved back to the first position relative to the inner frame 550, the pocket closure 580 can assume its first configuration as shown in FIG. 9A.

**[0059]** In some embodiments of a prosthetic heart valve, an additional material layer can be attached to the inner frame in addition to the outer covering described above for previous embodiments (e.g., outer covering 160). The additional material layer can be attached to an inner face or an outer face of the inner frame of the valve. For example, the additional material layer can be attached to an inner face of the inner frame and outside of the leaflets of the valve. In other words, the outer covering can be disposed between the leaflets and the additional material layer, with all three components (leaflets, outer covering and additional material layer) disposed on an inner side of the inner frame of the valve. The additional material layer may be desirable to prevent possible billowing of the belly area of the leaflet. Such billowing can occur, for example, when backpressure that can cause the leaflets to close also applies pressure to the belly area of the leaflets, potentially causing them to bulge out into the pocket area towards the outer frame. The additional material layer can be composed of a variety of different materials. FIGS. 10A-10C illustrate a prosthetic heart valve 600 that includes such a material layer 625. In this embodiment, the material layer 625 is disposed as a cylinder that covers an inner frame 650 from a base 622 of the inner frame 650 to a peak or atrium end 624 of the inner frame 650. As shown in FIGS. 10A and 10B, the valve 600 includes leaflets 670. As shown in FIG. 10C, the cylindrically disposed material layer 625 bridges the peaks 624 of the frame 650. In an alternative embodiment, the material layer can be configured to follow the shape of the inner frame as shown in FIG. 10D. In this embodiment, a valve 600' includes a material layer 625' that substantially follows or conforms to the shape of the inner frame 650. In other words, the material layer 625' spans between frame portions of the inner frame 650. In some embodiments, the material layers 625, 625' can be, for example, a polyester material.

## Claims

**1.** A prosthetic heart valve (400), comprising:

an inner frame (450) having an open end portion (447);

an outer frame (420) having an open end portion (416) and coupled to the inner frame at its other end such that the outer frame and the inner frame, when the outer frame is in a first position relative to the inner frame, define an annular region (485) between a portion of the inner frame and a portion of the outer frame that is open toward the open end portion of the outer frame and the open end portion of the inner frame, and the outer frame being movable between the first position relative to the inner frame in which the outer frame is in a biased expanded configuration and a second position relative to the inner frame in which the outer frame is inverted relative to the inner frame; **characterised by**

a stretchable pocket covering (480) coupled to the inner frame and coupled to the outer frame such that an open end of the annular space is covered by the pocket covering between the open end portion of the inner frame and the open end portion of the outer frame,
the stretchable pocket covering configured to move between a first configuration in which the pocket covering has a first length when the outer frame is in the first position relative to the inner frame and a second configuration in which the pocket covering has a second length greater than the first length when the outer frame is in the second position relative to the inner frame.

**2.** The prosthetic heart valve (400) of claim 1, wherein the pocket covering (480), the inner frame (450) and outer frame (420) collectively define a pocket (485) in which thrombus can form and be retained when the prosthetic heart valve is disposed within a heart of a patient.

**3.** The prosthetic heart valve (400) of claim 1, wherein when the outer frame (420) is in the first position, the open end portion (416) of the outer frame and the open end portion (447) of the inner frame (450) are each disposed in the same direction, when the outer frame is in the second position, the open end portion of the outer frame is disposed in an opposite direction as the open end portion of the inner frame.

**4.** The prosthetic heart valve (400) of claim 1, wherein the outer frame (420) is coupled to the inner frame (450) at multiple coupling joints (446), the inner frame includes a tether coupling portion opposite the open end portion (447) of the inner frame,

when the outer frame is in the first position, the coupling joints are disposed between the open end portion (416) of the outer frame and the tether coupling portion of the inner frame,
when the outer frame is in the second position, the coupling joints are disposed between the open end portion of the inner frame and the open end portion of the outer frame.

**5.** The prosthetic heart valve (400) of claim 1, wherein the pocket covering (480) is formed of a material having a porosity that is sufficiently large to allow red blood cells to pass through the pocket closure into the pocket (485) and that is sufficiently small to prevent thrombus formed from the red blood cells to pass through the pocket closure from the pocket.

**6.** The prosthetic heart valve (400) of claim 1, wherein the pocket covering (480) is formed of a braided Nitinol material.

**7.** The prosthetic heart valve (400) of claim 1, wherein the pocket covering (480) is formed of a shape memory material configured to be moved from a biased configuration to an elongated configuration and back to the biased configuration.

**8.** The prosthetic heart valve (400) of claim 1, further comprising:

an outer covering (260) disposed on the inner frame (450);
leaflets (270) disposed within an interior of the inner frame; and
a cylindrical material layer (625) disposed about the outer covering, the cylindrical material layer configured to prevent billowing of a belly area of the leaflets into the annular region.

**9.** The prosthetic heart valve (400) of claim 1, further comprising:

an outer covering (260) disposed on the inner frame (450);
leaflets (270) disposed within an interior of the inner frame; and
a material layer (625) disposed over the outer covering and conforming to the shape of the inner frame, the material layer configured to prevent billowing of a belly area of the leaflets into the annular region.

**10.** A prosthetic heart valve (500), comprising:

an inner frame (550) having an open end portion (547);
an outer frame (520) having an open end portion (516) and coupled to the inner frame at its other end such that the outer frame and the inner frame, when the outer frame is in a first position relative to the inner frame, define an annular region (585) between a portion of the inner frame and a portion of the outer frame that is open toward the open end portion of the outer frame and the open end portion of the inner frame, and the outer frame being movable between the first position relative to the inner frame in which the outer frame is in a biased expanded configuration and a second position relative to the inner frame in which the outer frame is inverted relative to the inner frame; **characterised by**
a pocket covering (580) having a first portion (584) coupled to a stretchable second portion (586), the first portion being coupled to the outer frame at a first coupling joint (587), the second portion being coupled to the outer frame at a second coupling joint (589), the pocket covering enclosing the annular space,
the pocket covering configured to move be-

tween a first configuration in which the second portion of the pocket covering has a first length when the outer frame is in the first position relative to the inner frame and a second configuration in which the second portion of the pocket covering has a second length greater than the first length when the outer frame is in the second position relative to the inner frame.

**11.** The prosthetic heart valve (500) of claim 10, wherein the pocket covering (580) and the outer frame (520) collectively define a pocket (585) in which thrombus can form and be retained when the prosthetic heart valve is disposed within a heart of a patient.

**12.** The prosthetic heart valve (500) of claim 10, wherein when the outer frame (520) is in the first position, the open end portion (516) of the outer frame and the open end portion (547) of the inner frame (550) are each disposed in the same direction, when the outer frame is in the second position, the open end portion of the outer frame is disposed in an opposite direction as the open end portion of the inner frame.

**13.** The prosthetic heart valve (500) of claim 10, wherein the outer frame (520) is coupled to the inner frame (550) at multiple coupling joints (546), the inner frame includes a tether coupling portion opposite the open end portion of the inner frame,

when the outer frame is in the first position, the coupling joints are disposed between the open end portion of the outer frame and the tether coupling portion of the inner frame,
when the outer frame is in the second position, the coupling joints are disposed between the open end portion of the inner frame and the open end portion of the outer frame.

**14.** The prosthetic heart valve (500) of claim 10, wherein the pocket closure (580) is formed of a material having a porosity that is sufficiently large to allow red blood cells to pass through the pocket closure into the pocket (585) and that is sufficiently small to prevent thrombus formed from the red blood cells to pass through the pocket closure from the pocket.

**15.** The prosthetic heart valve (500) of claim 10, wherein the pocket covering (580) is formed of a braided Nitinol material.

**16.** The prosthetic heart valve (500) of claim 10, wherein the pocket covering (580) is formed of a shape memory material configured to be to be moved from a biased configuration to an elongated configuration and back to the biased configuration.

**17.** The prosthetic heart valve (500) of claim 10, further comprising:

an outer covering (260) disposed on the inner frame (550);
leaflets (270) disposed within an interior of the inner frame; and
a cylindrical material layer (625) disposed about the outer covering, the cylindrical material layer configured to prevent billowing of a belly area of the leaflets into the annular region.

**18.** The prosthetic heart valve (500) of claim 10, further comprising:

an outer covering (260) disposed on the inner frame (550);
leaflets (270) disposed within an interior of the inner frame; and
a material layer (625) disposed over the outer covering and confirming to the shape of the inner frame, the material layer configured to prevent billowing of a belly area of the leaflets into the annular region.

**Patentansprüche**

**1.** Eine prothetische Herzklappe (400), die Folgendes umfasst:

einen inneren Rahmen (450) mit einem offenen Endabschnitt (447);
einen äußeren Rahmen (420), der einen offenen Endabschnitt (416) aufweist und an seinem anderen Ende mit dem inneren Rahmen gekoppelt ist, so dass der äußere Rahmen und der innere Rahmen, wenn sich der äußere Rahmen in einer ersten Position relativ zu dem inneren Rahmen befindet, einen ringförmigen Bereich (485) zwischen einem Abschnitt des inneren Rahmens und einem Abschnitt des äußeren Rahmens definiert, der zu dem offenen Endabschnitt des äußeren Rahmens und dem offenen Endabschnitt des inneren Rahmens hin offen ist, wobei
der äußere Rahmen zwischen der ersten Position relativ zum inneren Rahmen, in der sich der äußere Rahmen in einer vorgespannten expandierten Konfiguration befindet, und einer zweiten Position relativ zum inneren Rahmen beweglich ist, in der der äußere Rahmen relativ zum inneren Rahmen invertiert ist;
**gekennzeichnet durch** eine dehnbare Taschenabdeckung (480), die mit dem inneren Rahmen verbunden ist und die mit dem äußeren Rahmen verbunden ist, sodass ein offenes Ende des ringförmigen Raums durch die Taschenabdeckung zwischen dem offenen Endabschnitt des inneren Rahmens und dem offe-

nen Endabschnitt des äußeren Rahmens abgedeckt ist,
wobei die dehnbare Taschenabdeckung konfiguriert ist, sich zwischen einer ersten Konfiguration, in der die Taschenabdeckung eine erste Länge aufweist, wenn sich der äußere Rahmen in der ersten Position relativ zum inneren Rahmen befindet, und einer zweiten Konfiguration zu bewegen, in der die Taschenabdeckung eine zweite Länge aufweist, die größer ist als die erste Länge, wenn sich der äußere Rahmen in der zweiten Position relativ zum inneren Rahmen befindet.

**2.** Die prothetische Herzklappe (400) nach Anspruch 1, wobei die Taschenabdeckung (480), der innere Rahmen (450) und der äußere Rahmen (420) gemeinsam eine Tasche (485) definieren, in der sich ein Thrombus bilden kann und zurückgehalten werden kann, wenn die Herzklappenprothese in einem Herzen eines Patienten angeordnet ist.

**3.** Die prothetische Herzklappe (400) nach Anspruch 1, wobei, wenn sich der äußere Rahmen (420) in der ersten Position befindet, der offene Endabschnitt (416) des äußeren Rahmens und der offene Endabschnitt (447) des inneren Rahmens (450) jeweils in der gleichen Richtung angeordnet sind, und wenn sich der äußere Rahmen in der zweiten Position befindet, der offene Endabschnitt des äußeren Rahmens in einer entgegengesetzten Richtung wie der offene Endabschnitt des inneren Rahmens angeordnet ist.

**4.** Die prothetische Herzklappe (400) nach Anspruch 1, wobei der äußere Rahmen (420) mit dem inneren Rahmen (450) an mehreren Verbindungsgelenken (446) gekoppelt ist, und wobei der innere Rahmen einen Halteband-Kopplungsabschnitt gegenüber dem offenen Endabschnitt (447) des inneren Rahmens aufweist,

wobei, wenn sich der äußere Rahmen in der ersten Position befindet, die Verbindungsgelenke zwischen dem offenen Endabschnitt (416) des äußeren Rahmens und dem Halteband-Kopplungsabschnitt des inneren Rahmens angeordnet sind, und
wobei, wenn sich der äußere Rahmen in der zweiten Position befindet, die Verbindungsgelenke zwischen dem offenen Endabschnitt des inneren Rahmens und dem offenen Endabschnitt des äußeren Rahmens angeordnet sind.

**5.** Die prothetische Herzklappe (400) nach Anspruch 1, wobei die Taschenabdeckung (480) aus einem Material mit einer Porosität gebildet ist, die ausreichend groß ist, damit rote Blutkörperchen durch die Taschenabdeckung in die Tasche (485) gelangen können, und die ausreichend klein ist, um zu verhindern, dass aus den roten Blutkörperchen gebildete Thromben durch die Taschenabdeckung aus der Tasche gelangen.

**6.** Die prothetische Herzklappe (400) nach Anspruch 1, wobei die Taschenabdeckung (480) aus einem geflochtenen Nitinol-Material gebildet ist.

**7.** Die prothetische Herzklappe (400) nach Anspruch 1, wobei die Taschenabdeckung (480) aus einem Material mit Formgedächtnis gebildet ist, das so konfiguriert ist, dass es von einer vorgespannten Konfiguration in eine längliche Konfiguration und zurück in die vorgespannte Konfiguration bewegt werden kann.

**8.** Die prothetische Herzklappe (400) nach Anspruch 1, die ferner Folgendes umfasst:

eine äußere Abdeckung (260), die auf dem inneren Rahmen (450) angeordnet ist;
Klappensegel (270), die im Inneren des inneren Rahmens angeordnet sind; und
eine zylindrische Materialschicht (625), die auf der äußeren Abdeckung angeordnet ist, wobei die zylindrische Materialschicht konfiguriert ist, ein Aufblähen eines Bauchbereichs der Klappensegel in den ringförmigen Bereich zu verhindern.

**9.** Die prothetische Herzklappe (400) nach Anspruch 1, die ferner Folgendes umfasst:

eine äußere Abdeckung (260), die auf dem inneren Rahmen (450) angeordnet ist;
Klappensegel (270), die im Inneren des inneren Rahmens angeordnet sind; und
eine Materialschicht (625), die auf der äußeren Abdeckung angeordnet ist und die Form des inneren Rahmens annimmt, wobei die Materialschicht konfiguriert ist, ein Aufblähen eines Bauchbereichs der Klappensegel in den ringförmigen Bereich zu verhindern.

**10.** Eine prothetische Herzklappe (500), die Folgendes umfasst:

einen inneren Rahmen (550) mit einem offenen Endabschnitt (547);
einen äußeren Rahmen (520), der einen offenen Endabschnitt (516) aufweist und an seinem anderen Ende mit dem inneren Rahmen verbunden ist, so dass der äußere Rahmen und der innere Rahmen, wenn sich der äußere Rahmen in einer ersten Position relativ zum inneren Rah-

men befindet, einen ringförmigen Bereich (585) zwischen einem Abschnitt des inneren Rahmens und einem Abschnitt des äußeren Rahmens definieren, der zum offenen Endabschnitt des äußeren Rahmens und zum offenen Endabschnitt des inneren Rahmens hin offen ist, wobei

der äußere Rahmen zwischen der ersten Position relativ zum inneren Rahmen, in der sich der äußere Rahmen in einer vorgespannten expandierten Konfiguration befindet, und einer zweiten Position relativ zum inneren Rahmen beweglich ist, in der der äußere Rahmen relativ zum inneren Rahmen invertiert ist;

**gekennzeichnet durch** eine Taschenabdeckung (580) mit einem ersten Abschnitt (584), der mit einem dehnbaren zweiten Abschnitt (586) verbunden ist, wobei der erste Abschnitt an einer ersten Verbindungsstelle (587) mit dem äußeren Rahmen verbunden ist, der zweite Abschnitt an einer zweiten Verbindungsstelle (589) mit dem äußeren Rahmen verbunden ist und die Taschenabdeckung den ringförmigen Raum umschließt,

wobei die Taschenabdeckung konfiguriert ist, sich zwischen einer ersten Konfiguration, in der der zweite Abschnitt der Taschenabdeckung eine erste Länge aufweist, wenn sich der äußere Rahmen in der ersten Position relativ zum inneren Rahmen befindet, und einer zweiten Konfiguration zu bewegen, in der der zweite Abschnitt der Taschenabdeckung eine zweite Länge aufweist, die größer als die erste Länge ist, wenn sich der äußere Rahmen in der zweiten Position relativ zum inneren Rahmen befindet.

**11.** Die prothetische Herzklappe (500) nach Anspruch 10, wobei die Taschenabdeckung (580) und der äußere Rahmen (520) gemeinsam eine Tasche (585) definieren, in der sich ein Thrombus bilden und zurückgehalten werden kann, wenn die Herzklappenprothese in einem Herzen eines Patienten angeordnet ist.

**12.** Die prothetische Herzklappe (500) nach Anspruch 10 , wobei, wenn sich der äußere Rahmen (520) in der ersten Position befindet, der offene Endabschnitt (516) des äußeren Rahmens und der offene Endabschnitt (547) des inneren Rahmens (550) jeweils in der gleichen Richtung angeordnet sind, und wenn sich der äußere Rahmen in der zweiten Position befindet, der offene Endabschnitt des äußeren Rahmens in einer entgegengesetzten Richtung wie der offene Endabschnitt des inneren Rahmens angeordnet ist.

**13.** Die prothetische Herzklappe (500) nach Anspruch 10 , wobei der äußere Rahmen (520) mit dem inneren Rahmen (550) an mehreren Verbindungsgelenken (546) gekoppelt ist, wobei der innere Rahmen gegenüber dem offenen Endabschnitt des inneren Rahmens einen Halteband-Kopplungsabschnitt aufweist,

wobei, wenn sich der äußere Rahmen in der ersten Position befindet, die Verbindungsgelenke zwischen dem offenen Endabschnitt des äußeren Rahmens und dem Haltband-Kopplungsabschnitt des inneren Rahmens angeordnet sind, und

wobei, wenn sich der äußere Rahmen in der zweiten Position befindet, die Verbindungsgelenke zwischen dem offenen Endabschnitt des inneren Rahmens und dem offenen Endabschnitt des äußeren Rahmens angeordnet sind.

**14.** Die prothetische Herzklappe (500) nach Anspruch 10 , wobei die Taschenabdeckung (580) aus einem Material mit einer Porosität gebildet ist, die ausreichend groß ist, damit rote Blutkörperchen durch die Taschenabdeckung in die Tasche (585) gelangen können, und die ausreichend klein ist, um zu verhindern, dass aus den roten Blutkörperchen gebildete Thromben durch die Taschenabdeckung aus der Tasche gelangen.

**15.** Die prothetische Herzklappe (500) nach Anspruch 10, wobei die Taschenabdeckung (580) aus einem geflochtenen Nitinol-Material gebildet ist.

**16.** Die prothetische Herzklappe (500) nach Anspruch 10, wobei die Taschenabdeckung (580) aus einem Material mit Formgedächtnis gebildet ist, das so konfiguriert ist, dass es von einer vorgespannten Konfiguration in eine längliche Konfiguration und zurück in die vorgespannte Konfiguration bewegt werden kann.

**17.** Die prothetische Herzklappe (500) nach Anspruch10, die ferner Folgendes umfasst:

eine äußere Abdeckung (260), die auf dem inneren Rahmen (550) angeordnet ist;

Klappensegel (270), die im Inneren des inneren Rahmens angeordnet sind; und

eine zylindrische Materialschicht (625), die um die äußere Abdeckung herum angeordnet ist, wobei die zylindrische Materialschicht konfiguriert ist, ein Aufblähen eines Bauchbereichs der Klappensegel in den ringförmigen Bereich hinein zu verhindern.

**18.** Die prothetische Herzklappe (500) nach Anspruch10, die ferner Folgendes umfasst:

eine äußere Abdeckung (260), die auf dem inneren Rahmen (550) angeordnet ist;
Klappensegel (270), die im Inneren des inneren Rahmens angeordnet sind; und
eine Materialschicht (625), die auf der äußeren Abdeckung angeordnet ist und die Form des inneren Rahmens annimmt, wobei die Materialschicht konfiguriert ist, ein Aufblähen eines Bauchbereichs der Klappensegel in den ringförmigen Bereich zu verhindern.

**Revendications**

**1.** Valve cardiaque prothétique (400), comprenant :

un cadre intérieur (450) ayant une partie d'extrémité ouverte (447) ;
un cadre extérieur (420) ayant une partie d'extrémité ouverte (416) et couplé au cadre intérieur à son autre extrémité de sorte que le cadre extérieur et le cadre intérieur, lorsque le cadre extérieur est dans une première position par rapport au cadre intérieur, définissent une région annulaire (485) entre une partie du cadre intérieur et une partie du cadre extérieur qui est ouverte vers la partie d'extrémité ouverte du cadre extérieur et la partie d'extrémité ouverte du cadre intérieur, et
le cadre extérieur étant mobile entre la première position par rapport au cadre intérieur dans laquelle le cadre extérieur est dans une configuration déployée sollicitée et une seconde position par rapport au cadre intérieur dans laquelle le cadre extérieur est inversé par rapport au cadre intérieur ; et
un revêtement de poche extensible (480) couplé au cadre intérieur et couplé au cadre extérieur de sorte qu'une extrémité ouverte de l'espace annulaire est couverte par le revêtement de poche entre la partie d'extrémité ouverte du cadre intérieur et la partie d'extrémité ouverte du cadre extérieur,
le revêtement de poche extensible configuré pour se déplacer entre une première configuration dans laquelle le revêtement de poche a une première longueur lorsque le cadre extérieur est dans la première position par rapport au cadre intérieur et une seconde position dans laquelle le revêtement de poche a une seconde longueur supérieure à la première longueur lorsque le cadre extérieur est dans la seconde position par rapport au cadre intérieur.

**2.** Valve cardiaque prothétique (400) selon la revendication 1, dans laquelle le revêtement de poche (480), le cadre intérieur (450) et le cadre extérieur (420) définissent collectivement une poche (485) dans laquelle un thrombus peut se former et être retenu lorsque la valve cardiaque prothétique est disposée dans le coeur d'un patient.

**3.** Valve cardiaque prothétique (400) selon la revendication 1, dans laquelle, lorsque le cadre extérieur (420) est dans la première position, la partie d'extrémité ouverte (416) du cadre extérieur et la partie d'extrémité ouverte (447) du cadre intérieur (450) sont chacune disposées dans la même direction, lorsque le cadre extérieur est dans la seconde position, la partie d'extrémité ouverte du cadre extérieur est disposée dans une direction opposée à celle de la partie d'extrémité ouverte du cadre intérieur.

**4.** Valve cardiaque prothétique (400) selon la revendication 1, dans laquelle le cadre extérieur (420) est couplé au cadre intérieur (450) au niveau de multiples joints de couplage (446), le cadre intérieur comprend une partie de couplage d'attache opposée à la partie d'extrémité ouverte (447) du cadre intérieur,

lorsque le cadre extérieur est dans la première position, les joints de couplage sont disposés entre la partie d'extrémité ouverte (416) du cadre extérieur et la partie de couplage d'attache du cadre intérieur,
lorsque le cadre extérieur est dans la seconde position, les joints de couplage sont disposés entre la partie d'extrémité ouverte du cadre intérieur et la partie d'extrémité ouverte du cadre extérieur.

**5.** Valve cardiaque prothétique (400) selon la revendication 1, dans laquelle le revêtement de poche (480) est formé d'un matériau ayant une porosité qui est suffisamment grande pour permettre aux globules rouges de passer à travers la revêtement de poche dans la poche (485) et qui est suffisamment petite pour empêcher le thrombus formé à partir des globules rouges de passer à travers la revêtement de poche depuis la poche.

**6.** Valve cardiaque prothétique (400) selon la revendication 1, dans laquelle le revêtement de poche (480) est formé d'un matériau Nitinol tressé.

**7.** Valve cardiaque prothétique (400) selon la revendication 1, dans laquelle le revêtement de poche (480) est formé d'un matériau à mémoire de forme configuré pour être déplacé d'une configuration inclinée à une configuration allongée et revenir à la configuration inclinée.

**8.** Valve cardiaque prothétique (400) de la revendication 1, comprenant en outre :

un revêtement extérieur (260) disposé sur le ca-

dre intérieur (450) ;
des feuillets (270) disposés à l'intérieur du cadre intérieur; et
une couche de matériau cylindrique (625) disposée autour du revêtement extérieur, la couche de matériau cylindrique étant configurée pour empêcher le gonflement d'une zone ventrale des feuillets dans la région annulaire.

**9.** Valve cardiaque prothétique (400) de la revendication 1, comprenant en outre :

un revêtement extérieur (260) disposé sur le cadre intérieur (450) ;
des feuillets (270) disposés à l'intérieur du cadre intérieur; et
une couche de matériau (625) disposée sur le revêtement extérieur et se conformant à la forme du cadre intérieur, la couche de matériau étant configurée pour empêcher le gonflement d'une zone ventrale des feuillets dans la région annulaire.

**10.** Une valve cardiaque prothétique (500), comprenant :

un cadre intérieur (550) ayant une partie d'extrémité ouverte (547) ;
un cadre extérieur (520) ayant une partie d'extrémité ouverte (516) et couplé au cadre intérieur à son autre extrémité de sorte que le cadre extérieur et le cadre intérieur, lorsque le cadre extérieur est dans une première position par rapport au cadre intérieur, définissent une région annulaire (585) entre une partie du cadre intérieur et une partie du cadre extérieur qui est ouverte vers la partie d'extrémité ouverte du cadre extérieur et la partie d'extrémité ouverte du cadre intérieur, et
le cadre extérieur étant mobile entre la première position par rapport au cadre intérieur dans laquelle le cadre extérieur est dans une configuration déployée sollicitée et une seconde position par rapport au cadre intérieur dans laquelle le cadre extérieur est inversé par rapport au cadre intérieur ; et
un revêtement de poche (580) ayant une première partie (584) couplée à une seconde partie étirable (586), la première partie étant couplée au cadre extérieur au niveau d'un premier joint de couplage (587), la seconde partie étant couplée au cadre extérieur au niveau d'un second joint de couplage (589), le revêtement de poche enfermant l'espace annulaire,
le revêtement de poche configuré pour se déplacer entre une première configuration dans laquelle la seconde partie du revêtement de poche a une première longueur lorsque le cadre extérieur est dans la première position par rapport au cadre intérieur et une seconde position dans laquelle la seconde partie du revêtement de poche a une seconde longueur supérieure à la première longueur lorsque le cadre extérieur est dans la seconde position par rapport au cadre intérieur.

**11.** Valve cardiaque prothétique (500) de la revendication 10, dans laquelle le revêtement de poche (580) et le cadre extérieur (520) définissent collectivement une poche (585) dans laquelle un thrombus peut se former et être retenu lorsque la valve cardiaque prothétique est disposée à l'intérieur du coeur d'un patient.

**12.** Valve cardiaque prothétique (500) selon la revendication10 , dans laquelle, lorsque le cadre extérieur (520) est dans la première position, la partie d'extrémité ouverte (516) du cadre extérieur et la partie d'extrémité ouverte (547) du cadre intérieur (550) sont chacune disposées dans la même direction, lorsque le cadre extérieur est dans la seconde position, la partie d'extrémité ouverte du cadre extérieur est disposée dans une direction opposée à celle de la partie d'extrémité ouverte du cadre intérieur.

**13.** Valve cardiaque prothétique (500) selon la revendication10, dans laquelle le cadre extérieur (520) est couplé au cadre intérieur (550) au niveau de multiples joints de couplage (546), le cadre intérieur comprend une partie de couplage d'attache opposée à la partie d'extrémité ouverte du cadre intérieur,

lorsque le cadre extérieur est dans la première position, les joints de couplage sont disposés entre la partie d'extrémité ouverte du cadre extérieur et la partie de couplage d'attache du cadre intérieur,
lorsque le cadre extérieur est dans la seconde position, les joints de couplage sont disposés entre la partie d'extrémité ouverte du cadre intérieur et la partie d'extrémité ouverte du cadre extérieur.

**14.** Valve cardiaque prothétique (500) selon la revendication10, dans laquelle le revêtement de poche (580) est formée d'un matériau ayant une porosité qui est suffisamment grande pour permettre aux globules rouges de passer à travers le revêtement de poche dans la poche (585) et qui est suffisamment petite pour empêcher le thrombus formé à partir des globules rouges de passer à travers le revêtement de poche depuis la poche.

**15.** Valve cardiaque prothétique (500) selon la revendi-

cation 10, dans laquelle le revêtement de poche (580) est formé d'un matériau Nitinol tressé.

**16.** Valve cardiaque prothétique (500) selon la revendication 10, dans laquelle le revêtement de poche (580) est formé d'un matériau à mémoire de forme configuré pour être déplacé d'une configuration inclinée à une configuration allongée et revenir à la configuration inclinée.

**17.** Valve cardiaque prothétique (500) de la revendication10, comprenant en outre :

un revêtement extérieur (260) disposé sur le cadre intérieur (550) ;
des feuillets (270) disposés à l'intérieur du cadre intérieur; et
une couche de matériau cylindrique (625) disposée autour du revêtement extérieur, la couche de matériau cylindrique étant configurée pour empêcher le gonflement d'une zone ventrale des feuillets dans la région annulaire.

**18.** Valve cardiaque prothétique (500) de la revendication10, comprenant en outre :

un revêtement extérieur (260) disposé sur le cadre intérieur (550) ;
des feuillets (270) disposés à l'intérieur du cadre intérieur; et
une couche de matériau (625) disposée sur le revêtement extérieur et confirmant la forme du cadre intérieur, la couche de matériau étant configurée pour empêcher le gonflement d'une zone ventrale des feuillets dans la région annulaire.

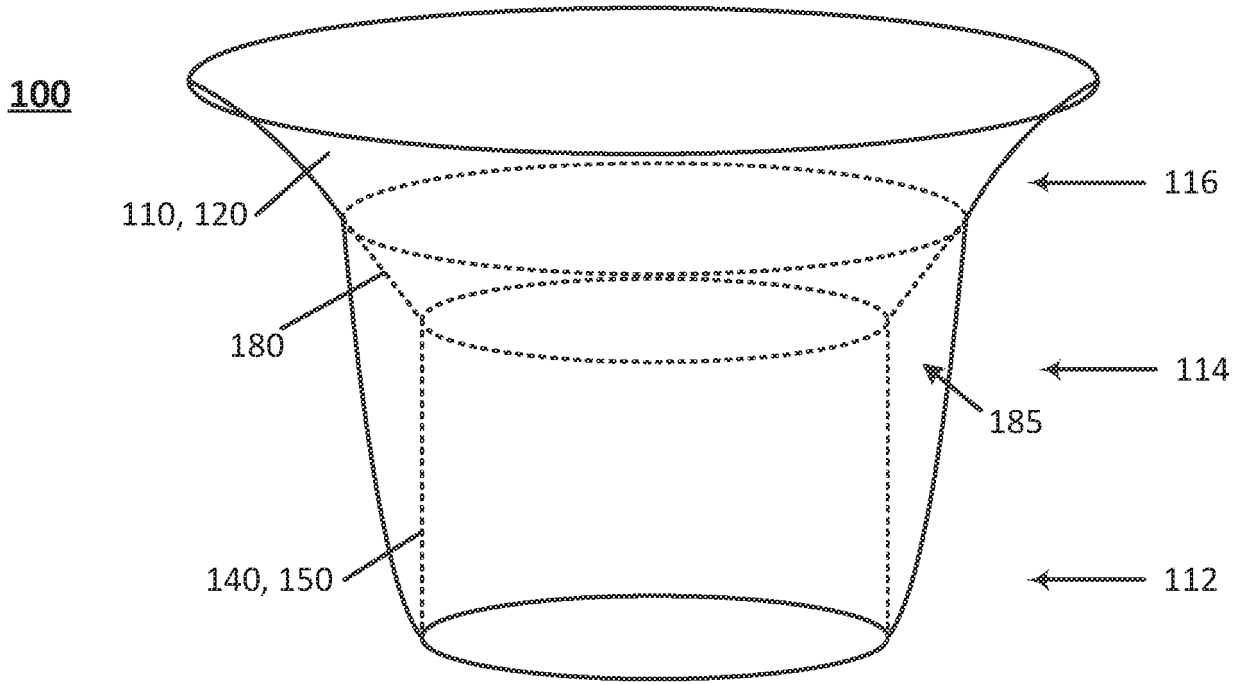

100
110, 120
116
180
114
185
140, 150
112

FIG. 1A

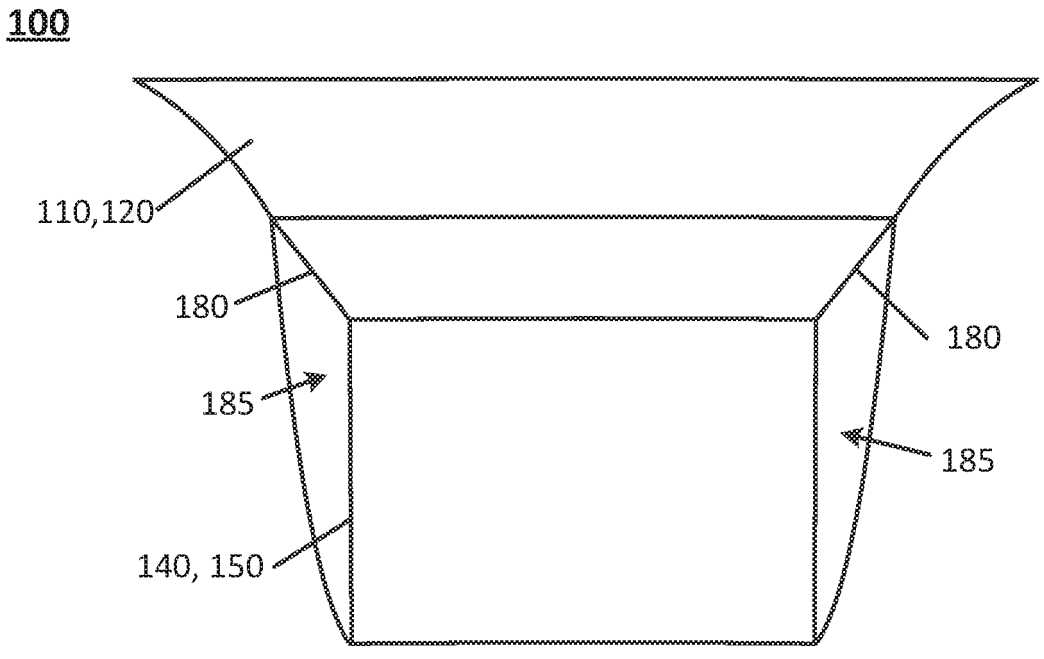

100
110,120
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185
185
140, 150

FIG. 1B

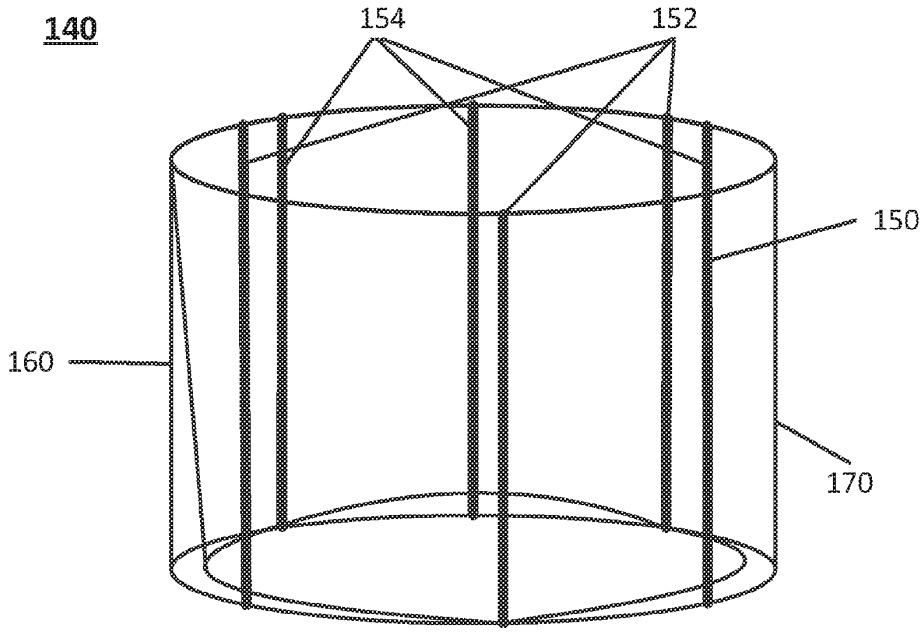



FIG. 2A

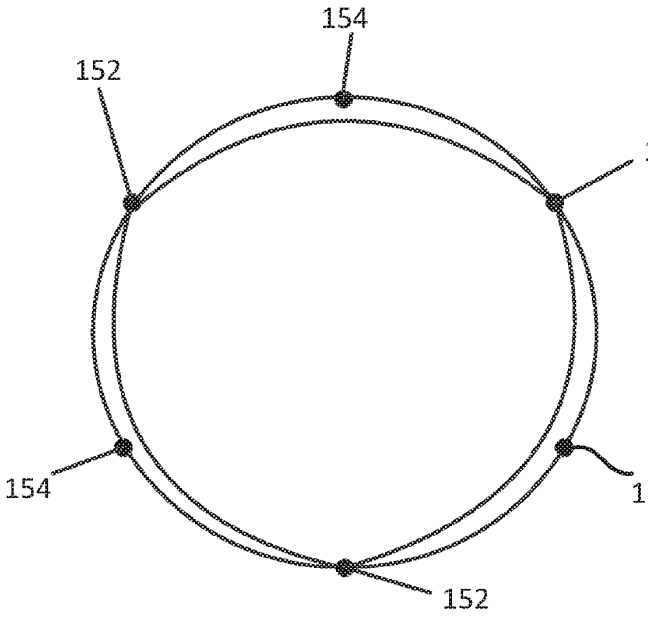



FIG. 2B

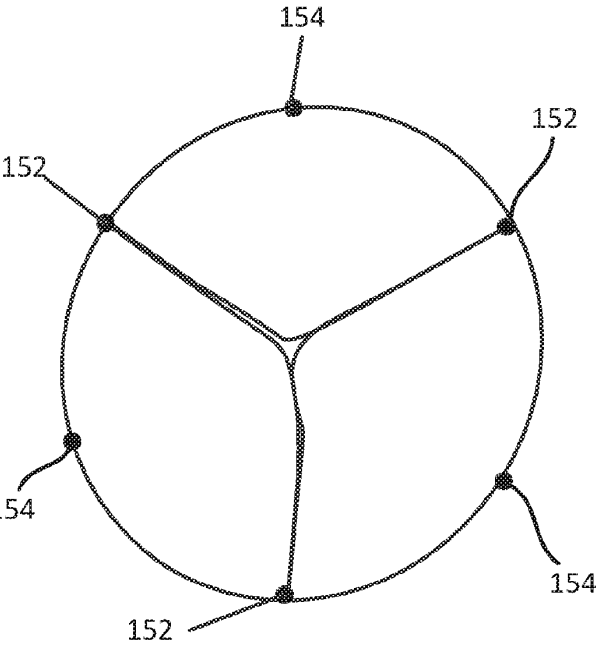



FIG. 2C

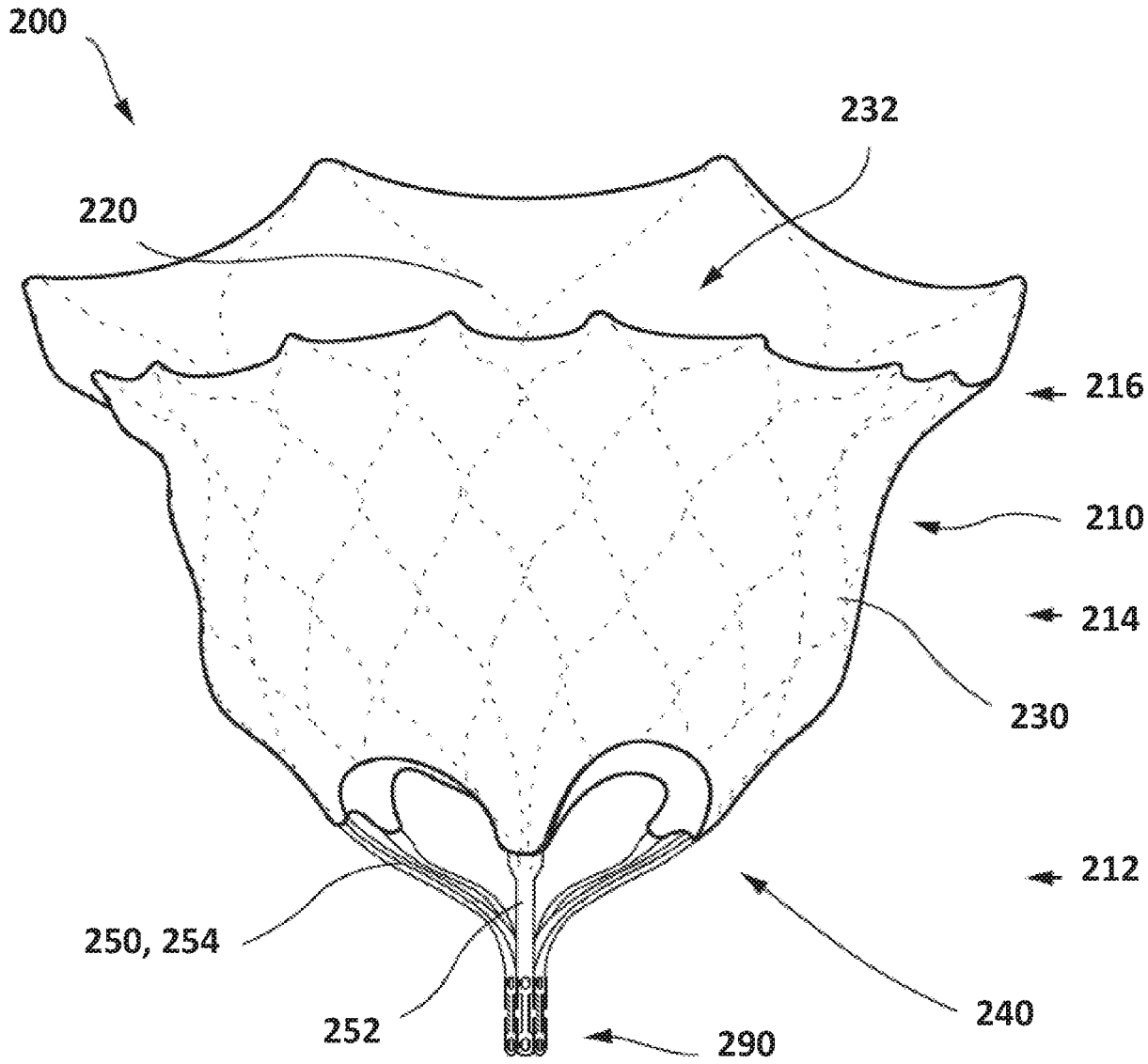



FIG. 3

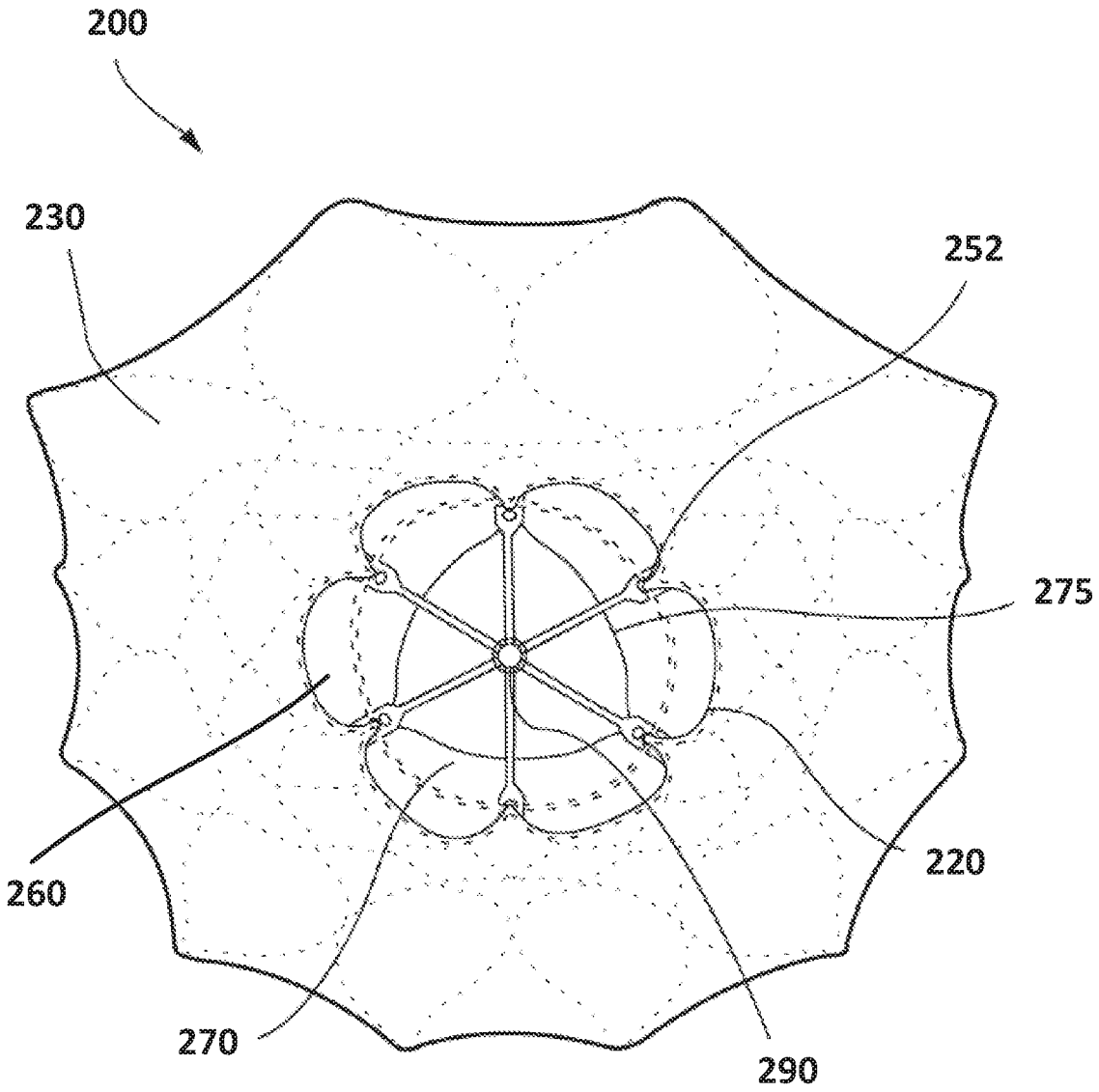



FIG. 4

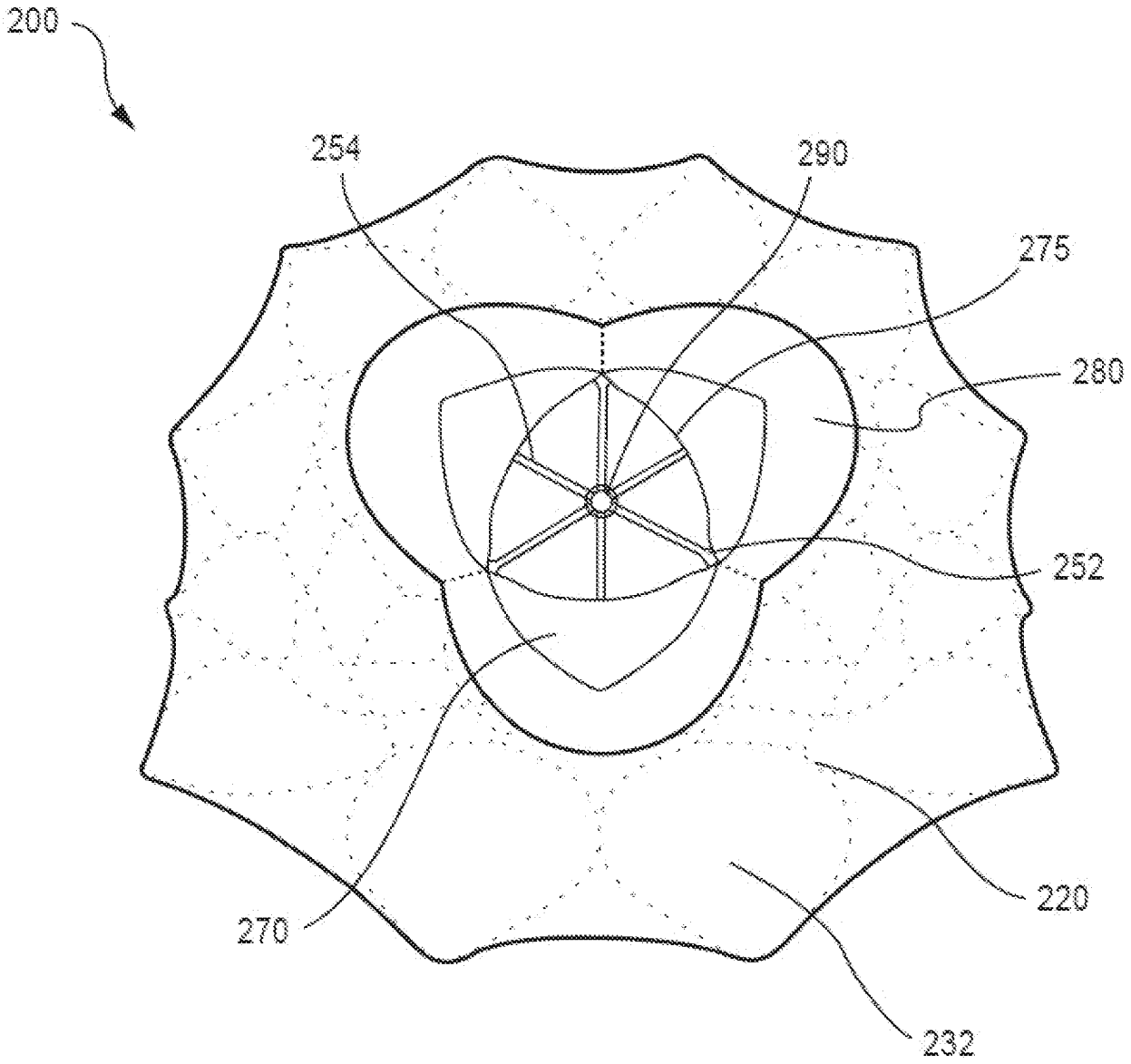



FIG. 5

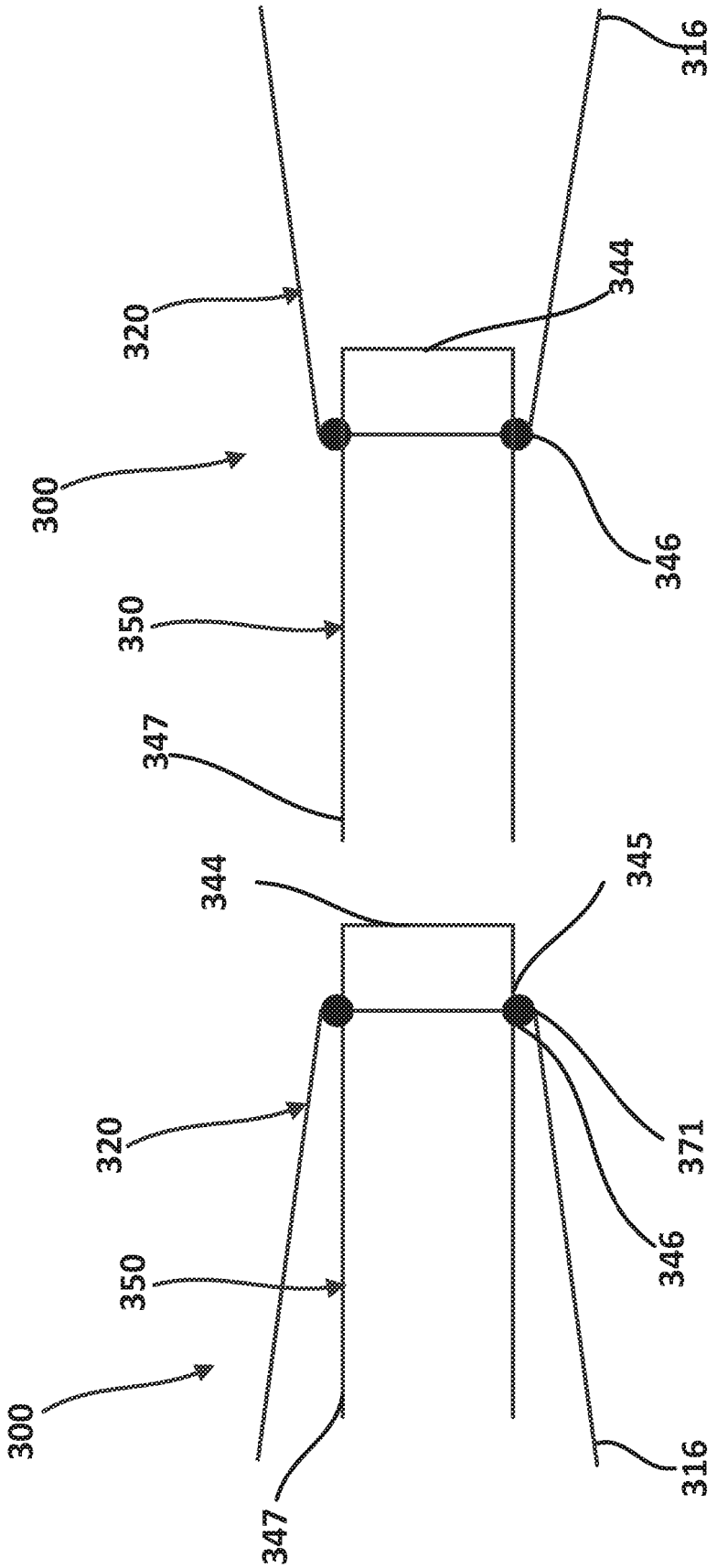



FIG. 6A

FIG. 6B

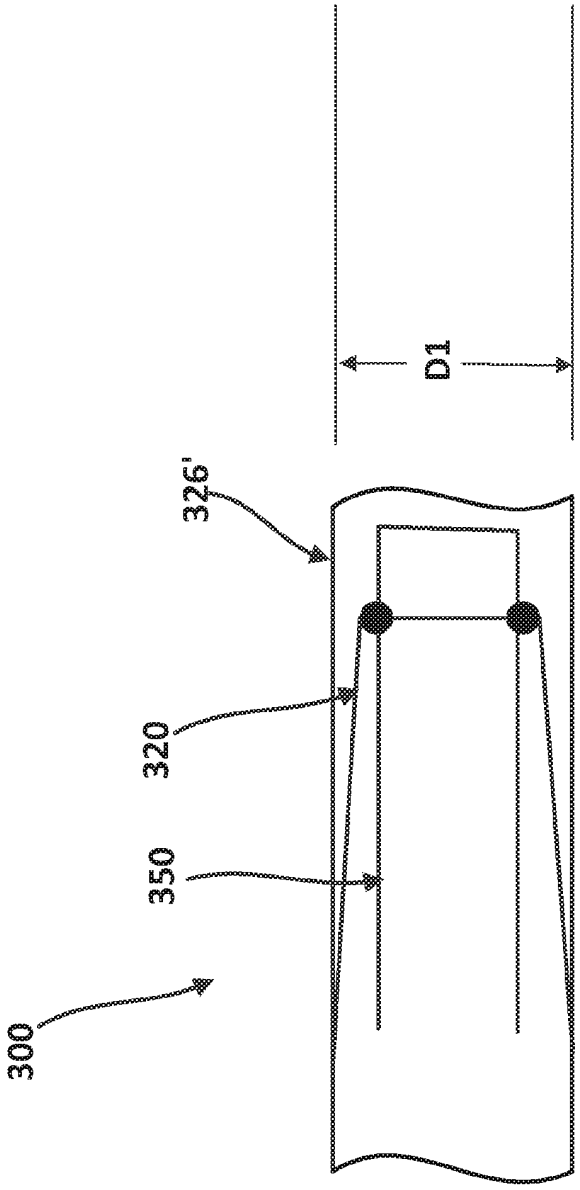



FIG. 6C

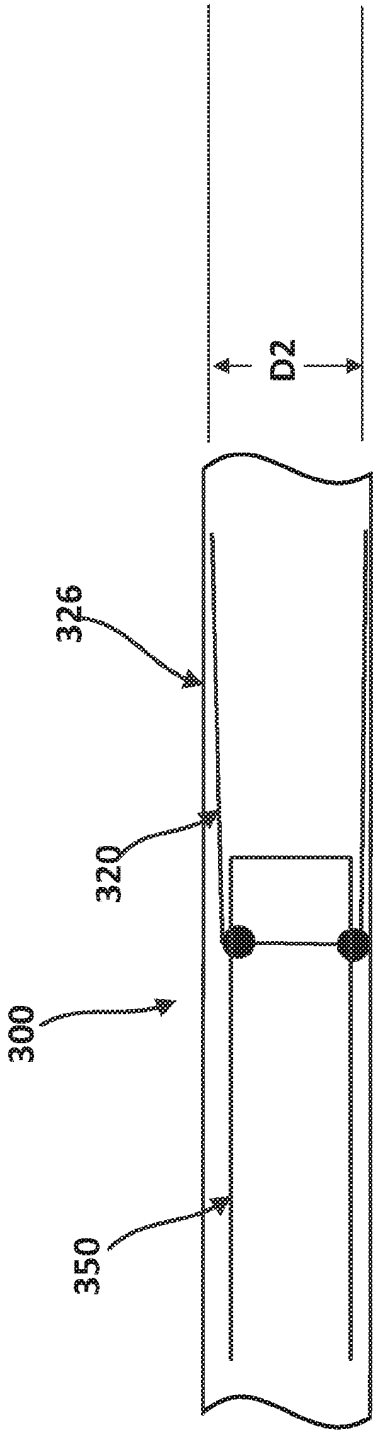



FIG. 6D

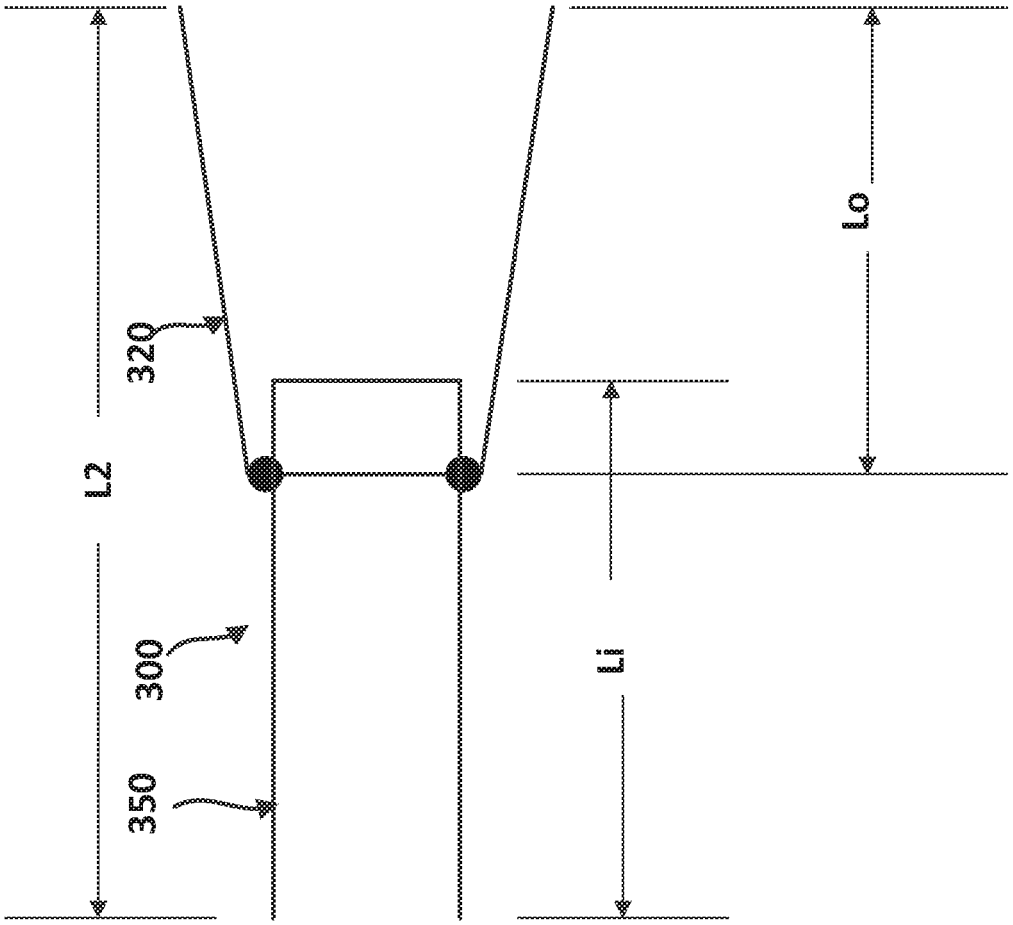



FIG. 7B

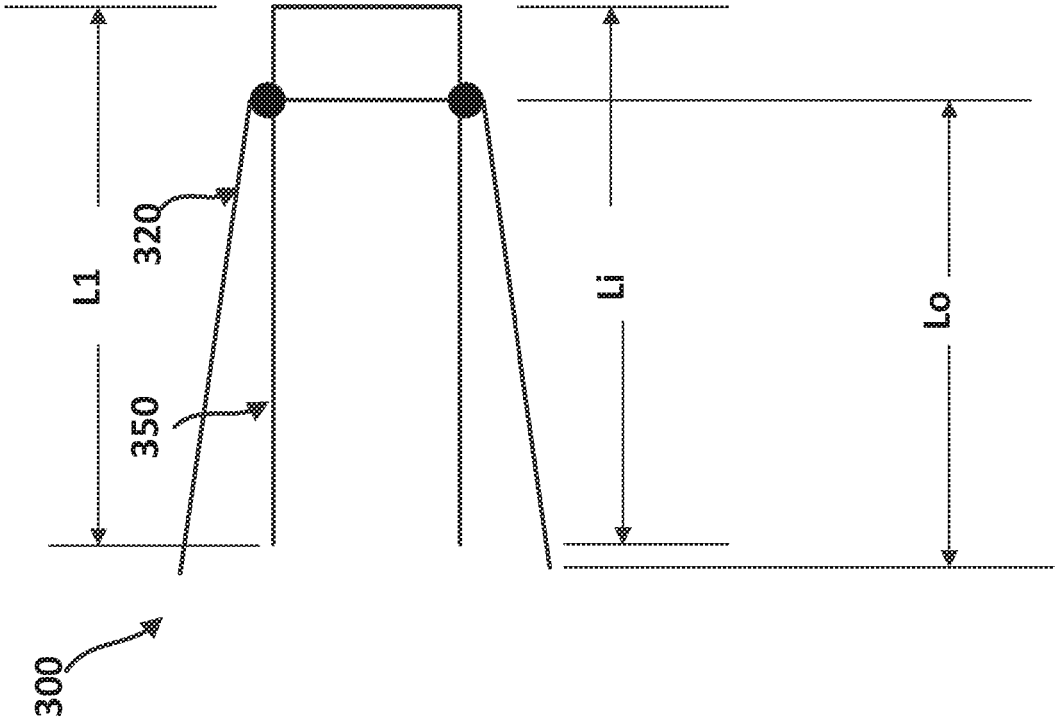



FIG. 7A

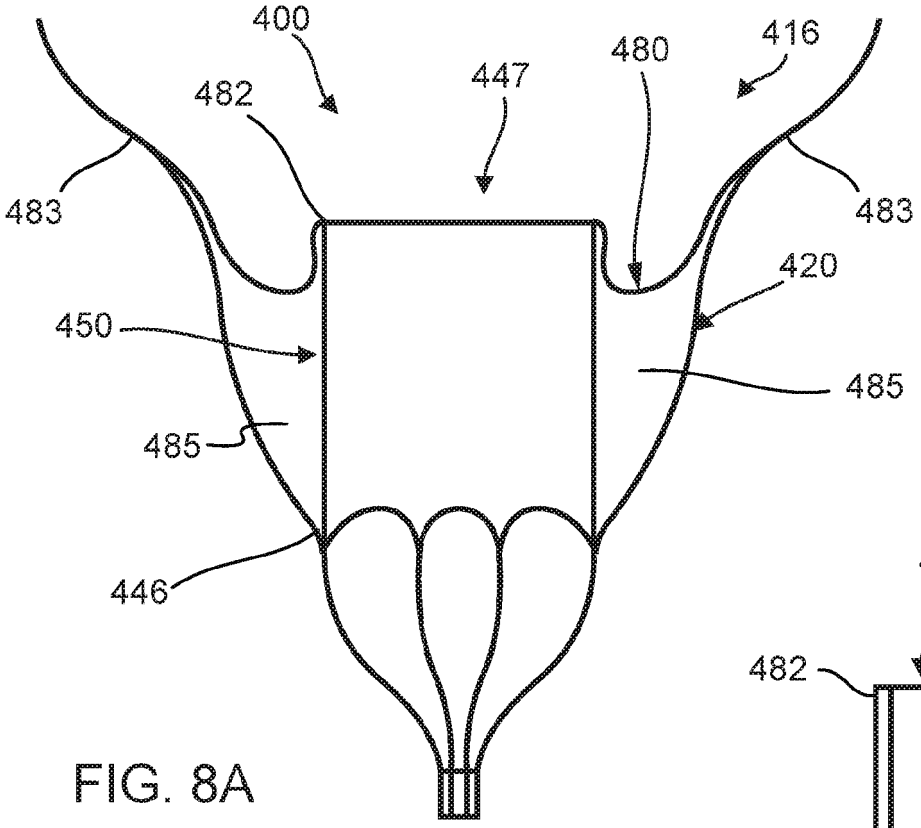

400
482
447
480
416
483
483
420
450
485
485
446

FIG. 8A

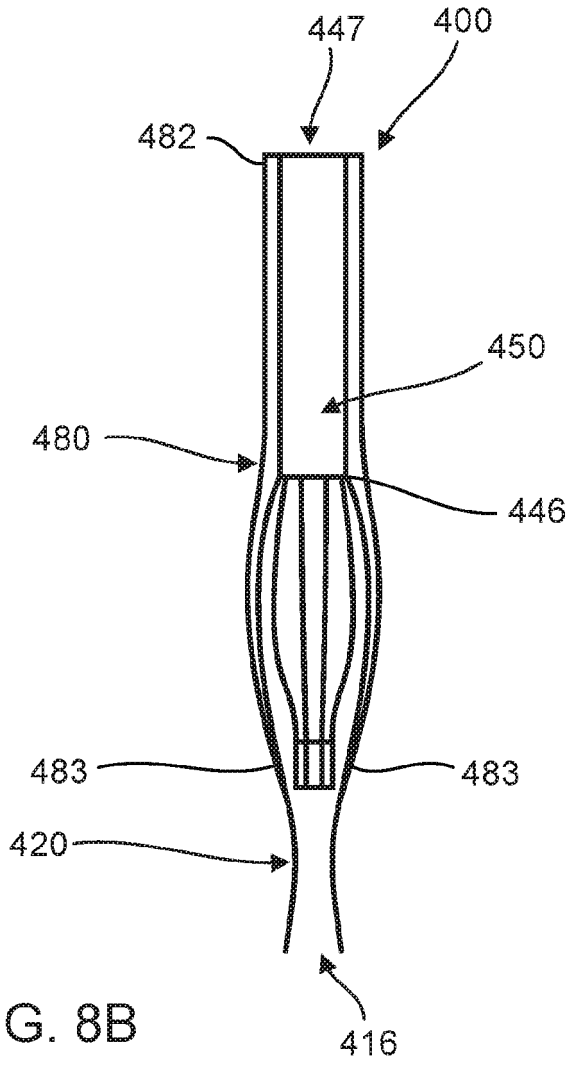

447
400
482
450
480
446
483
483
420
416

FIG. 8B

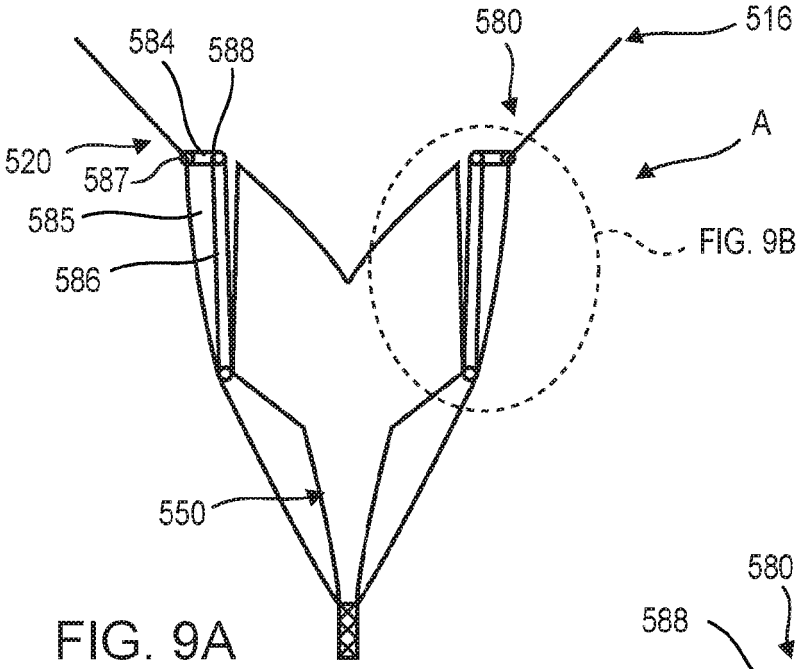



FIG. 9A

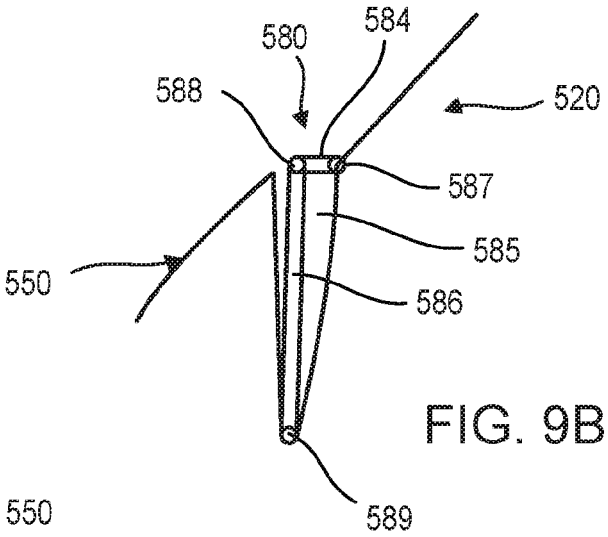



FIG. 9B

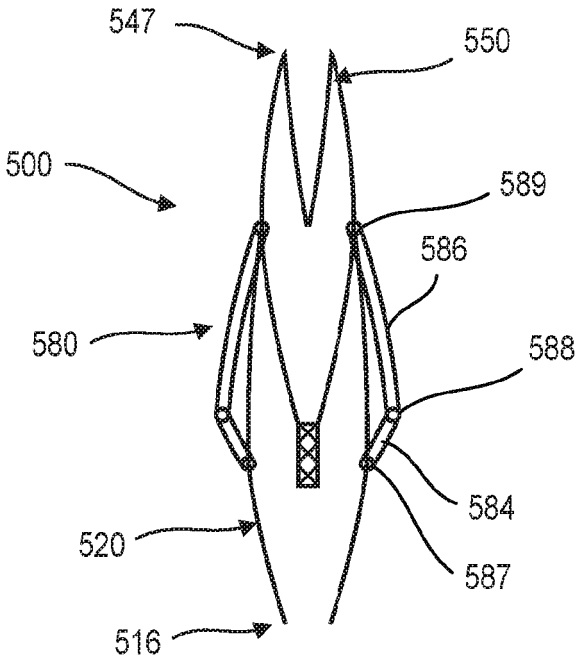



FIG. 9C

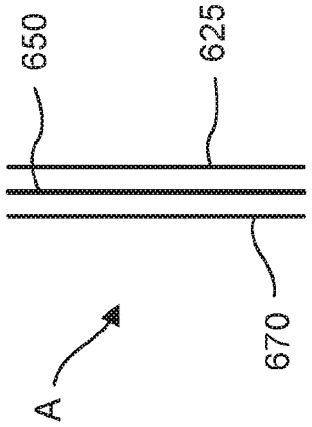



FIG. 10B

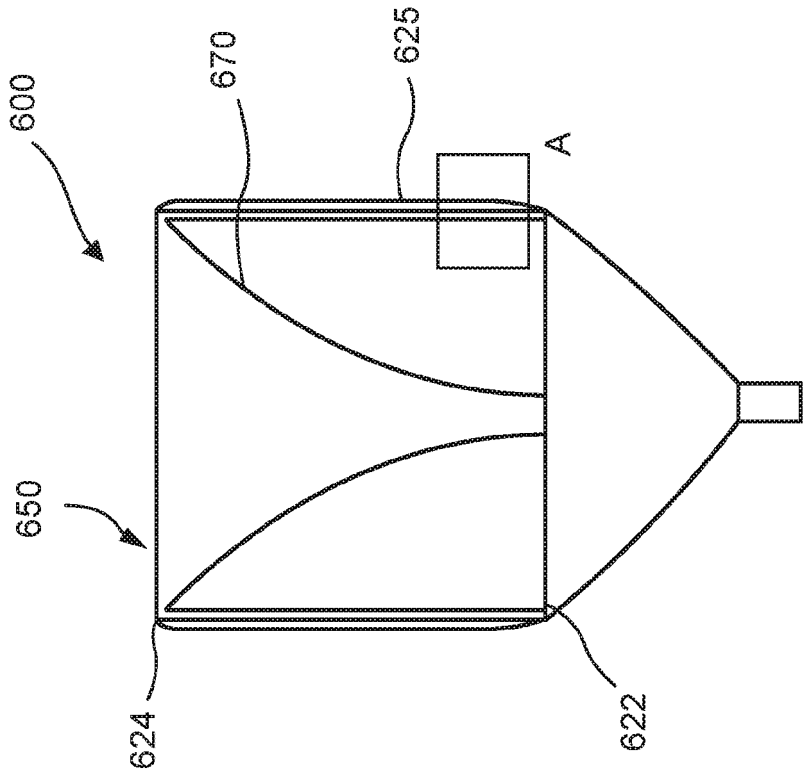



FIG. 10A

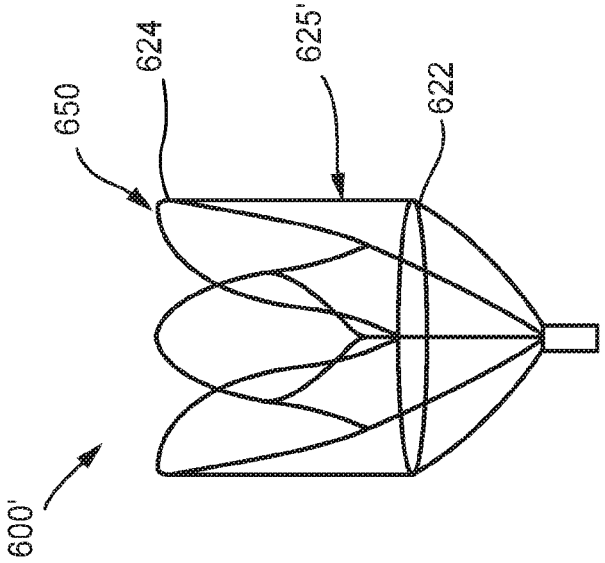



FIG. 10D

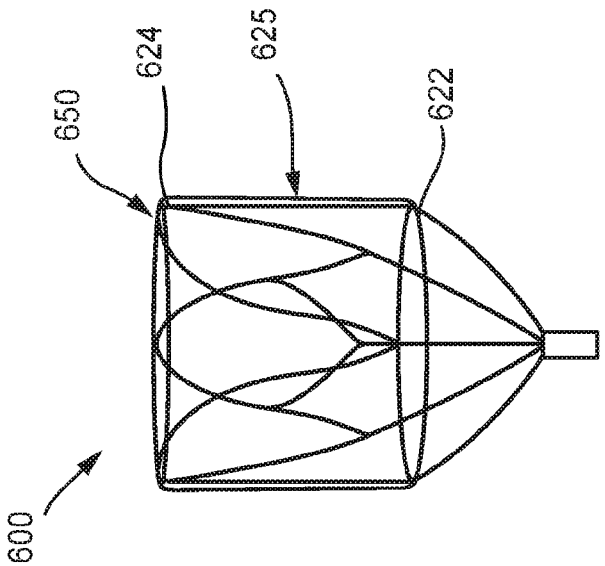



FIG. 10C

## REFERENCES CITED IN THE DESCRIPTION

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